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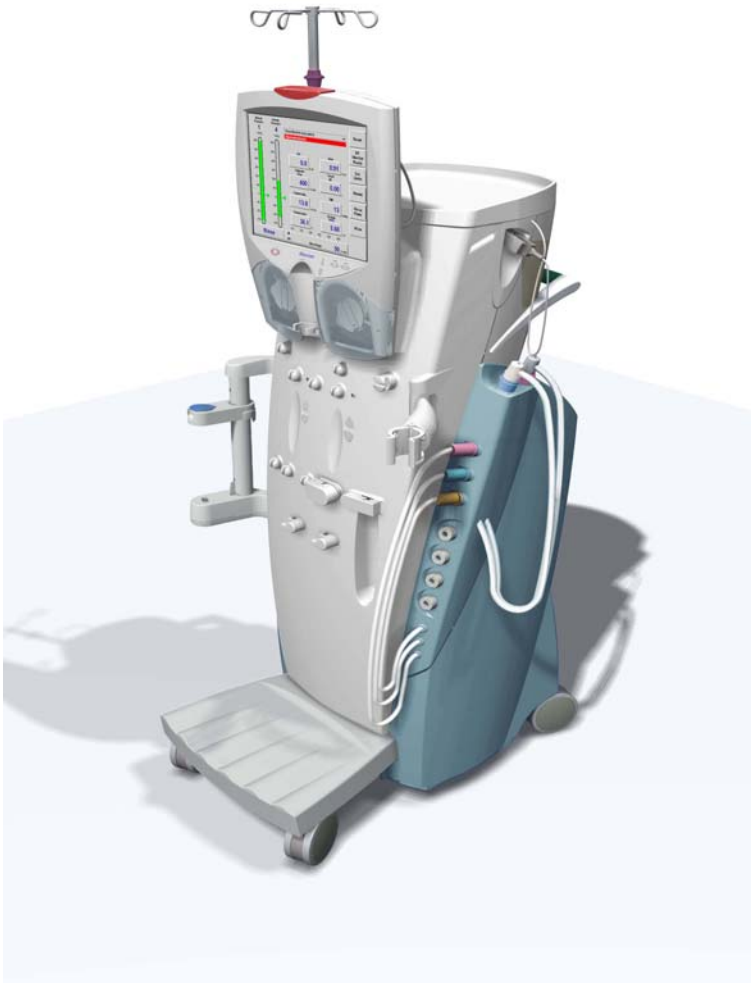
ARENA Hemodialysis Instrument Service Manual



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April 2004

SERVICE MANUAL

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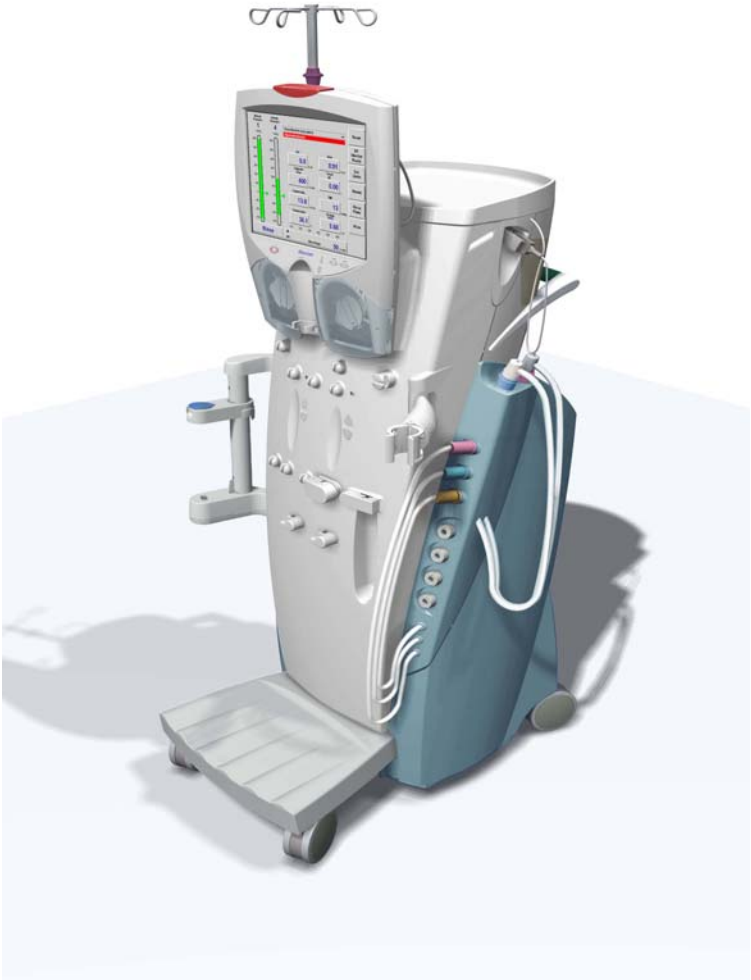

Notes to Users

Federal (U. S. A.) law restricts this device to sale by or on the order of a physician.

The **Arena** Instrument is manufactured and intended for use only as indicated in the labeling and prescribed by a physician.

The safe and effective treatment of acute or chronic uremia depends primarily upon the medical skills and knowledge of the attending physician. Consequently, technical competence in operation of the **Arena** Instrument must be supplemented by a thorough understanding of the associated medical procedures. This total knowledge can be gained only through training given by recognized medical authorities.

Upon completing such training, the user must operate the system in accordance with the information detailed in the operator's manual. However, patient treatment must at all times be in accordance with specific procedures prescribed by a qualified physician.

Read all warnings, precautions, and instructions included in the *Arena Hemodialysis Instrument Operator's Manual* carefully before using the Instrument. The operator's manual provides the information necessary for the proper operation of the **Arena** Instrument. It is not a guide to the administration of hemodialysis.

This *Service Manual* provides instructions required for all Instrument service procedures.

For information on dialysis, a good reference is *Review of Hemodialysis for Nurses and Dialysis Personnel,* sixth edition, 1999, by C.F. Gutch, Martha H. Stoner, Anna L. Corea. It is published by Mosby Inc., 11830 Westline Industrial Drive, St. Louis, Mo 63146.

WARNING

Electric Shock Hazard. Do not attempt to perform any of the procedures described in this manual unless you have been properly trained on the Instrument.

Do not attempt to repair any electronics unless you are properly trained and qualified in this kind of work.

Never perform any maintenance, calibration, verification, or part replacement on this Instrument while a patient is connected.

Before attempting to perform any repair, calibration, or replacement in the hydraulic and pneumatic systems, you must first run a complete disinfection cycle to minimize the risk of contamination. The use of gloves and eye protection are recommended.

Modification, alteration, or lack of maintenance procedures as prescribed in this manual, may adversely affect the safety and efficacy of this device. The manufacturer is not responsible for any malfunctions as a result of alteration, use of non-Baxter replacement parts, neglect or misuse.

BAXTER HEALTHCARE CORP.
DEERFIELD, IL. 60015 U. S. A.

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Arena

1. INTRODUCTION

1.1 GENERAL

The **Arena** Hemodialysis Instrument, hereinafter called the Instrument, is comprised of the components required to perform an automated hemodialysis treatment according to the product specifications. It combines the functions necessary for a dialysis treatment with volumetric ultrafiltration control, bicarbonate dialysis and profiled sodium, bicarbonate and ultrafiltration.

This manual provides readily available information regarding care, theory of operation, preventive maintenance, calibrations, troubleshooting, and repairs for the Instrument.

This service manual is a support document for properly trained service and maintenance personnel on the Instrument. It is not intended to be used by anyone who has not received formal training on the Instrument.

A glossary of terms and abbreviations used in this manual is included in Section 29.

The service technician must:

- Have a basic knowledge of electronics and hydraulics.
- Have a basic knowledge of troubleshooting and preventive maintenance techniques.
- Be thoroughly familiar with the contents of the operator's and service manuals.
- Be sufficiently trained in the operation and maintenance of this Instrument and able to distinguish normal from aberrant Instrument behavior.
- Be certified by Baxter as trained to service **Arena** Instruments.

The Instrument must:

- Be in good working order and certified as such by the attending physician.
- Be operated only in accordance with the Instrument specifications listed by Baxter and with the operating instructions contained within the Instrument operator's manual and Instrument labeling. The attending physician is responsible for any changes to the procedures.

1.2 INSTRUMENT DESCRIPTION

The Instrument provides dialysate at the prescribed temperature and ionic concentration to be used for hemodialysis treatment. It has the ability to monitor Instrument, dialysate and blood circuit functions during dialysis. The Instrument is based on volumetric proportioning, volumetric ultrafiltration control and digital electronics. Instrument and treatment parameters are displayed on a 15-inch LCD video display. Operator control is done through an interactive touch screen, and control panel, which also makes the Instrument very easy to use and clean.

The Instrument offers a wide range of blood and dialysate flow rates, a choice of acid and bicarbonate concentrate types and a choice in method of delivery: central acid and/or bicarbonate, individual liquid acid, and individual liquid or powder bicarbonate.

This Instrument features a Patient Data Card Reader, high blood flow rate capacity (up to 650 mL/min), automatic ultrafiltration control, standard and variable bicarbonate and sodium dialysis capabilities, sodium bolus delivery control, and patient profiling. The Instrument has automated cleaning with heat disinfection, and chemical disinfection using common chemicals like bleach and formaldehyde, plus other disinfectants like Actril, Dialox, and Doxan as standard features. The Instrument can operate with either bicarbonate or acetate concentrates.

The Instrument is also able to deliver single-needle dialysis with a single blood pump or with the addition of a secondary blood pump.

In case of any failure of the Instrument, the Instrument responds by stopping the treatment and placing the Instrument into a safe state.

The Instrument must use only water which is compliant with the standards set by AAMI for hemodialysis.

See Section 2 for a general description of the components of the Instrument.

1.3 CONFIGURATIONS AND OPTIONS

There are four basic configurations in which the Instrument can be ordered (some are not available in some countries):

- Single Pump (SP)
- Single Pump with Pressure Monitoring (SPP)
- Single Pump with Extras (SPX)
- Double Pump with Extras (DPX)

Each of these configurations has different standard and optional features as shown in this section.

1.3.1 Standard Features

Minimum standard features of every Instrument, regardless of the configuration, are:

- 15” color LCD display
- Automatic Chemical Disinfection
- Automatic Heat Clean Disinfection
- Automatic Start up
- Disinfect Infusion Monitor
- On-screen Sodium Button
- Sodium, Bicarbonate, and Ultrafiltration Profiling
- Extendable pole with four looped IV hooks
- Patient Data Card Reader
- Heparin Pump
- RS-232 communications
- Two concentrate containers, including wands
- One Disinfect Bottle
- Priming container (fluid catchall)
- Option Key
- CE Mark and IEC 60601 Compliant

1.3.2 Optional Features

These options may be installed at the factory or in the field. Some of these options are standard depending on the configuration. Other features may not be available in all markets.

	CONFIGURATION			
Feature	**SP** 1571278001	**SPP** 1571278002	**SPX** 1571278003	**DPX** 1571278004
120 VAC or 230 VAC Volts, EMC compliant	Select as needed	Select as needed	Select as needed	Select as needed
3-Light Status Lamp	Optional	Standard	Optional	Standard
Blood Pressure Monitor (NIBP)	Optional	Standard	Optional	Standard
Citric Acid Heat clean	Optional	Optional	Optional	Standard
Concentrate fitting panel mounted A	Optional	Optional	Optional	Optional
Concentrate fitting panel mounted B	Optional	Optional	Optional	Optional
Double Blood Pump, Single-Needle	Optional	Optional	Optional	Standard
Double Rotary Clamp	Not allowed	Not allowed	Optional	Standard
Extended Treatment Time (not allowed with OLHDF or Hemavision)	Optional	Optional	Optional	Optional
Hemavision	Optional	Optional	Optional	Optional
Hemodiafiltration with Scale	Optional	Optional	Optional	Optional
Language	Select as needed	Select as needed	Select as needed	Select as needed
On-line Hemodiafiltration (not allowed with Extended Treatment Time and HDF)	Not allowed	Not allowed	Optional	Optional
Powder Bicarbonate (export only)	Not allowed	Not allowed	Optional	Standard
Regulator, Acid Concentrate	Optional	Optional	Optional	Optional
Regulator, Bicarbonate Concentrate	Optional	Optional	Optional	Optional
Regulators, Dual Concentrate	Optional	Optional	Optional	Optional
Single Linear Clamp	Standard	Standard	Not allowed	Not allowed
Single Pump, Single Needle	Optional	Optional	Standard	Standard
Single Rotary Clamp	Optional	Optional	Standard	Not allowed
Sodium Button Pendant	Optional	Standard	Optional	Standard

1.4 GENERAL WARNINGS AND CAUTIONS

1.4.1 Definitions of Terms

A **WARNING** is a statement identifying conditions or practices that could result in personal injury or loss of life.

A **CAUTION** is a statement identifying conditions or practices that could result in equipment or other property damage.

1.4.2 Warnings

1.4.2.1 General

Federal law restricts this device to sale by or on order of a physician.

Do perform regular maintenance as described in this manual to ensure patient safety.

Do not operate this Instrument in an explosive environment or near flammable anesthetics.

1.4.2.2 Procedural

Do not under any circumstances perform calibrations or testing on this Instrument while dialysis is in progress.

Do not connect a patient to the Instrument during the installation tests.

To prevent the possible overfiltration of the patient during hemodiafiltration with commercially prepared sterile solutions, make sure that the second blood pump operates smoothly during the second pump stall test.

Use only bloodlines that have been approved by Baxter for use with this Instrument. Before a new style/type of bloodline is used with the Instrument, make sure the bloodline is compatible with the Instrument including: the air detector does not produce excessive false alarms and the line clamp occludes the tubing properly.

The air detector housing and blood line must be clean and dry for proper operation. Do not wet or apply other liquids to the air detector or external surface of the blood line in the air detector. Wetting or the use of other liquids (including ultrasonic gel) could result in reduced air detector sensitivity.

Setting the minimum TMP alarm limit above 0 mmHg (more positive) will require the removal of fluid from the

patient. Even with some high flux (high KUf) dialyzers fluid removal may be necessary even when the TMP alarm limit is set at a negative value.

Setting the minimum UF rate above 0 mmHg will remove fluid from the patient.

Water leaking from or found under the Instrument should be interpreted as an indication of a potential ultrafiltration error.

Do not enter data in Constant Entry without direct authorization from Baxter. If you inadvertently change a calibration constant or you are not sure if the present value is correct, remove the Instrument from service and contact Baxter for instructions.

After maintenance is completed, make sure that DIP Switches 1 and 2 are in the off position and the Instrument is hard powered off to remove it from the Calibration Mode.

After maintenance is completed, perform a complete functional test of the Instrument before returning it to clinical use.

Do make sure that all calibration Instruments are regularly calibrated against either primary standards or standards that are traceable to the National Institute for Standards and Technology (formerly National Bureau of Standards).

1.4.2.3 Electrical Safety

Electric Shock Hazard. Do not attempt to perform any of the procedures described in this manual unless you have been properly trained on the Instrument.

To prevent possible injury, the Instrument must be hard powered off (mains power switch off) before working with the fan. The fan may start without warning if the Instrument is soft powered off.

The Arena Instrument is intended to be operated with a mains ground system.

Make sure that the Instrument is properly grounded during operation. For patient safety, if the protective earth on the mains connector plug is broken or the protective earth wire is broken, repair before using. (Possible hazards may arise which may cause the allowable leakage current to be exceeded.)

This Instrument must be connected to an electrical circuit which is protected by a Ground Fault Circuit Interrupter (GFCI) or other leakage current protection device. The protection device must be tested periodically for proper operation.

When the Instrument is used in conjunction with other mains powered equipment, the use of the potential equalizer conductor is recommended between the equipment and the Instrument equipotential equalizer busbars. (Possible hazards may arise which may cause the allowable leakage current to be exceeded.)

Whenever a mains circuit is serviced or replaced, check the Instrument leakage current per local code.

Hard power off or disconnect cord before removing protective panels, soldering, replacing components, or replacing printed circuit boards.

Do not perform internal service or adjustment of this Instrument unless another person capable of rendering first aid and resuscitation is present.

High voltage may be present where the power cable enters the power entry assembly.

Use care when servicing the Instrument with power on or the Instrument plugged in. Dangerous voltages exist at several points in the Instrument. To avoid personal injury, do not touch exposed connections and components while power is applied.

Before performing any maintenance on the hydraulic system, turn off the power and the water.

Fuses should be replaced only by the same rating and only by a qualified service technician. Check for cause of the fuse failure.

1.4.2.4 OLHDF

For proper operation of the system and rinsing of the purge valves, Instruments with the On-Line HDF hardware must be customized for On-Line HDF.

1.4.2.5 Biohazard

Care should be taken when handling blood contaminated components to prevent contamination of personnel or other devices.

Handle used blood lines, dialyzers, internal pressure monitoring lines, internal and external transducer protectors, and other extracorporeal circuit components as potentially bio-hazardous waste. Refer to the clinic's procedures for the disposition of these items.

Make sure that the replacement of blood contaminated components is performed in an isolated area to help prevent contamination of personnel and other devices.

Make sure that all tools used to handle, access, remove and/or replace blood contaminated components are disinfected when the job is done to prevent contamination of personnel and/or other devices.

1.4.2.6 Disinfection/Cleaning

Instrument concentrate lines longer than 10' will affect the effectiveness of the heat clean and chemical disinfection cycle.

The concentrate lines from the central supply to the optional panel mount fittings are NOT part of the Instrument disinfection fluid path. These lines must be disinfected by the methods used for the central concentrate supply system.

Cleaning and reuse of the particle filter is not recommended.

Use of unapproved disinfectants may damage the dialysate filters and may change the microbial quality of the substitution fluid.

Manually starting Cool Down will abort the Heat Disinfection Mode. If Heat Clean is cancelled before completion, the Instrument must not be used on a patient until it is properly disinfected. This can be done by completing another Heat Clean cycle, or by performing a dwell Chemical Disinfect. Do not use single pass disinfectants because they will not completely disinfect the Instrument once any procedure with recirculation has been initiated and cancelled.

To prevent being burned, do not open the fluid path during the Heat Clean cycle.

Be careful when handling citric acid solutions. Read and follow the instructions for the safe handling of citric acid on the warning label on the citric acid bottle and follow the center's guidelines for use.

Make sure that the determination test shows a sufficiently low level of citric acid or disinfectant in the rinse solution before dialysis. Refer to the attending physician's directives for the acceptable limit and the AAMI standard for hemodialysis.

To ensure that the citric acid level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse solution in the dialysate lines.

Make sure that the determination test is specific for the chemical disinfectant used.

Before attempting to perform any repair, calibration, or replacement in the hydraulic and pneumatic systems, you must first run a complete disinfection cycle to minimize the risk of contamination. The use of gloves and eye protection is required. A disinfection cycle must also be run after replacing any parts in the hydraulics circuit.

Do not use any kind of non-approved disinfectant.

Never mix sodium hypochlorite with Formalin.

If the total viable microbial count is unacceptable, disinfect the water supply. Draw another sample after disinfecting and culture it to verify that the total viable microbial count has been reduced to acceptable levels before reconnecting to the Instrument.

Every time the Instrument is disinfected, and before proceeding with dialysis, verify that there are no residual disinfecting chemicals in the fluid path.

1.4.3 Cautions

1.4.3.1 Electrical

Use proper ESD protection when handling or contacting any ESD sensitive components.

Perform work using standard ESD precautions including personal grounding strap.

- **Static electrical charges may damage electronic components.**
- **Static damage may occur not only to integrated circuits mounted on the circuit board, but also to detached integrated circuits.**

- **Static damage may not be immediately evident.**
- **Static damage is cumulative.**
- **Both MOS and Bipolar integrated circuits may be damaged by discharge of static electricity.**
- **Both digital and linear integrated circuits may also be damaged.**

Always repackage the removed ROMs or boards in the original ESD packaging.

Do not remove or plug in any electronic component or assembly while power is applied to the Instrument.

Do not remove fuse from or insert fuses into any circuit board while power is applied to the board.

Fuses should be replaced only by the same rating and only by a qualified service technician. Check for cause of the fuse failure.

It is necessary to perform some of the adjustments with the covers removed. Use extra care to prevent fluids from entering or contacting the electronics of the Instrument.

1.4.3.2 Fluid

It is essential that all central concentrate supplies be equipped with a manual shut-off valve at each Instrument position. These shut off valves are required to prevent leaking when service is performed on the concentrate regulator or trunkline. These valves also prevent leakage when the female fitting shut off does not completely seal.

To reduce the chance of a major concentrate spill or leakage from the central concentrate line, it is recommended that the concentrate supply fitting with shut-off be installed.

The water used to prepare the concentrate must conform to the Association for the Advancement of Medical Instrumentation (AAMI), ISO, EP Purified Water or other local standards specific for water used in hemodialysis.

To prevent fluids from entering or contacting the electronics of this Instrument, do not operate the Instrument or perform any calibrations while the internal septa are not in place unless it is specifically required.

If clogging is the result of massive precipitate formation in the fluid path (such as might be caused by improper concentrate selection or preparation errors), particle filter backpressure

will increase as well. In these cases, acid rinses or heat clean cycles will not entirely remove the precipitates in the filters. The filters must be replaced.

1.4.3.3 Procedural

To prevent possible Instrument damage while unpacking, cut the box only along the line marked CUT ALONG LINE TO OPEN.

Storage at 0°C or less is possible only if the hydraulic circuit is completely drained. (See Section 27, Specifications.) If water remains in the Instrument and it freezes, the hydraulic system may be severely damaged.

1.4.3.4 Cleaning and Disinfection

Do not allow sodium hypochlorite to remain in the fluid path longer than the recommended time or damage may result.

Do not use other disinfecting agents or allow diluted sodium hypochlorite to dry on the external surfaces or damage may result.

Proper incoming water line disinfection must be followed in order to prevent heater damage.

1.4.4 Indications

The Instrument is indicated for use when a hollow fiber or parallel plate dialyzer is chosen for use in chronic or acute hemodialysis treatments including high-flux hemodialysis and on-line hemodiafiltration.

1.4.5 Contraindications

The Instrument is not intended to be a substitute for monitoring the patient's condition or extracorporeal circuit by trained and qualified personnel.

The Instrument is recommended for use only on patients whose prescriptions are within the minimum and maximum ranges of the Instrument, especially for values of minimum UF rate, UF rate error, dialysate flow range, minimum blood pump speed, air detector sensitivity, and extracorporeal volume (as defined in blood set labeling). It is not intended to be used outside of the device specifications or limitations.

The Instrument is not to be used with neonates.

1.5 RELATED PUBLICATIONS

- **Arena** Hemodialysis Instrument Operator's Manual
- **Arena** Replacement Parts Catalog

1.6 TOOLS AND TEST EQUIPMENT

The following tools and supplies are required to properly service the Instrument:

- **Arena** Patient Data Card
- Patient Data Card Reader/Writer
- Dialyzer and blood tubing set
- All acetate, acidified and bicarbonate concentrates that the unit uses
- Calibrated, true RMS multimeter, with a 3-1/2 digit display
- Calibrated conductivity, temperature, and pressure meter (NEO-2 or equivalent)
- Conductivity Recirculation Calibration Switch
- Assorted flat-blade and Phillips screwdrivers
- Torque screwdriver
- Assorted nut drivers and open-end ignition wrenches
- Assorted Allen wrenches
- Dentist mirror
- Flashlight
- Graduated containers, 250 cc and 3000 cc
- Two hemostats or tubing clamps
- Syringes, 60 cc (two), 30 cc, 10 cc
- Stopwatch
- High-vacuum silicone grease
- Fluid barriers
- Scale, 3000 g capacity, 0.1 g readability
- Loctite Fluid 242
- White RTV sealant
- Antistatic mat
- Magnet for service switch
- Calibration kit
- Potentiometer screwdriver

An optional laptop computer with the following minimum capabilities is recommended:

- CD-ROM reader
- 64 MB RAM
- 3 GB hard drive
- Pentium, 233 MHz or similar
- Acrobat Reader 4.0 or higher
- Modem, 33.6k

1.7 TESTING AFTER PARTS REPLACEMENT

All maintenance actions performed on the Instrument must be concluded with a complete calibration, verification, and testing of the system(s) impacted by the maintenance actions, including component swapping and replacing.

Refer to Section 19, Functional Verification, for detailed information.

1.8 MANUAL REVISIONS

From time to time there are changes in technical procedures and part numbers. Updates to this manual will be made by sections as listed in the Table of Contents. In each case, both the cover and the Table of Contents will also be updated to show the new revision date.

Information regarding these changes is distributed through Technical Service Bulletins, which are posted on the Internet, URL:

http://www.baxter.com/services/renal_services/technical_publications/index.html

You may also send your E-mail address to: tech_talk@baxter.com requesting *Technical Service Bulletin* notification and we will notify you by e-mail you when new information becomes available on the Internet.

This information may be available as hard copies, or on the Baxter Intranet.

1.9 QUESTIONS AND FEEDBACK

If you require further technical assistance in the USA, please call Baxter Instrument Services at **1-800-553-6898.** Outside the USA, please contact your local Baxter Technical Support Group.

All service personnel and other authorized users are encouraged to submit corrections and/or suggestions for the improvement of this document. They may be sent to:

Global Service
Baxter Healthcare Corporation
PO Box 1230
Pinellas Park, FL 33780-1230

You may also forward questions or feedback regarding the Instrument (technical issues, service and operator's manuals, parts catalog, etc.) to the following e-mail address:
renaltag@baxter.com

We will respond to you by the next business day.

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Arena

3. INSTRUMENT MODES

The term "mode" is used in this Instrument to describe a wide variety of states. This can be confusing unless you understand these modes both from an operator's perspective and from a service technician's perspective. Sections 3.1 through 3.3 will address the modes the Instrument goes through from power on through treatment, and then shutdown, Section 3.3 addresses certain options and the associated modes, then Section 3.4 will discuss the service modes.

3.1 PREPARATION FOR TREATMENT

This series of modes, or states, is summarized in the diagram and table below. It takes the Instrument from Hard Power On through Self Test, after which the operator can choose the next activity.

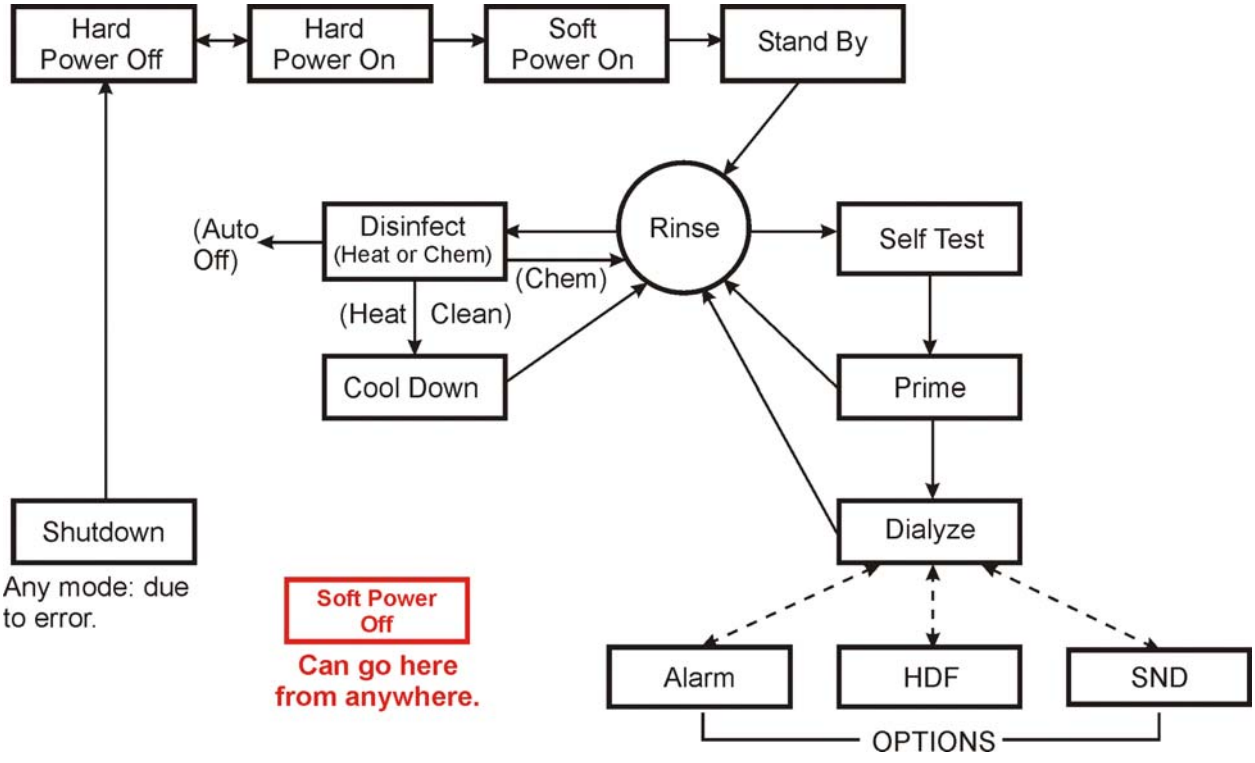

Table 2-1. Preparation Modes

Mode	Indications	Actions allowed/disallowed
Hard Power Off See section 5.2	No power is delivered to the instrument.	In this mode, normal operation or Calibration Mode is selected.
Hard Power On See Section 5.2	Backlight, alarm light, and BEEP on Power supply is turned on. Boards have power; all light up. Fan can operate if inside temperature requires it. Will turn "off" (SOFT POWER OFF) when completed	Turn soft power on. Select Calibration Mode.
Soft Power On See Section 5.2	After operator presses front panel power key, Instrument goes to Power On Mode.	
Power On	After a few seconds, Instrument goes to the Standby Mode.	
Standby	Stays here until you put it in Rinse Mode Proportioning pumps/heater are running. Dialysate temperature flow is set to the last used (can not be changed). Dialysate is in bypass. UF flow meter is on. Valves 1 and 4 are open until the Rinse Mode is activated. Rinse valve is open. TMP is around 200. Air and conductivity audible alarms, mutable, but recur every 1min. 40 sec. Event Timer functions and all following modes. NIBP version displayed and pressure accuracy verification	Can turn bypass LED off by pressing button Can NOT take a patient blood pressure reading Can use level buttons to check NIBP Can set blood pump speed (but not run blood pumps) Can go to Rinse Mode (if dialyzer connectors are on the rinse block) by pressing RINSE, then VERIFY Can not accept a Patient Data Card
Rinse	No air and conductivity audible alarms Audio alarms available for no supply, arterial pressure, venous pressure, or power failure Venous clamp open if dialyzer connectors are on the rinse block; closed if dialyzer connectors are off the rinse block Dialysate out of bypass and cycles every 45 seconds. UF rate automatically set at 3.60 L/h Pressures between flow equalizer cavities relieved so there is no excessive vacuum in flow path (dialysate pressure relief valve remains open) After concentrates are connected and normal conductivity & temperature are achieved, audible alarm beeps 3 times, main alarm lamp flashes, then SHUTDOWN TEST begins automatically.	Can go to heat/chemical cleaning Can take patient BP Blood pump speed can be set Can run the blood pump if dialysate lines are interlocked Dialysate flow and temperature can be set Standard sodium can be set Can operate bypass (will stay in bypass only 1 min.) but NOT break the interlock Can initiate SELF TEST by touching TEST then VERIFY
Self Test	Performs predialysis "operator tests"	

3.2 DURING TREATMENT

For each patient, the Instrument must first be primed, and then dialysis started. Although it is not a mode that is selected, the Instrument may also go into an alarm mode requiring action from the operator. The Prime, Dialyze and Alarm Modes are summarized below.

3.2.1 Prime Mode

3.2.1.1 Instrument status window display

PRIME

3.2.1.2 Instrument action

- The main alarm lamp flashes at a slow rate.
- The blood pump will operate.
- The venous line clamp is open.
- The self test has been successfully completed.
- The extracorporeal alarms may be disarmed.
- The extracorporeal alarms automatically armed if blood or ambient light is detected at the saline/blood detector.
- The UF rate may be manually set from the technician set minimum UF rate value to the maximum rate of 4.0 L/h.
- The Event Timer is available.
- Dialyzer Prime is available.
- The Instrument accepts a Patient Data Card.

If the extracorporeal alarms are armed:

- The arterial pressure alarm limit was set to ±50 mmHg around the indicated arterial pressure when the PRIME button was pressed or 10 seconds after the blood pump is turned on, off or rate changed, or the level adjust button pressed, or the RESET button touched.
- The venous pressure alarm limit is ±50 mmHg around the indicated venous pressure when the PRIME button was pressed or 10 seconds after the blood pump is turned on, off or rate changed, or the level adjust button pressed, or the RESET button touched.
- The TMP alarm limits are set to ±35 mmHg (within the range of the technician set minimum TMP value of -85 mmHg to a maximum of +500 mmHg) around the indicated pressure,

approximately 90 seconds after the blood pump is turned on, the blood pump rate is changed or the UF rate is changed, or the RESET button touched.

- The minimum low venous pressure alarm limit is approximately +10 mmHg.
- The air and blood leak detector instrument alarm responses are active.

If the extracorporeal alarms are disarmed:

- The arterial pressure alarm limits are –300 and +600 mmHg.
- The venous pressure alarm limits are ±200 mmHg around the indicated venous pressure when the ARMED / DISARM button is pressed or 10 seconds after the blood pump starts, blood pump power switch is turned off or the blood pump rate is changed, or the level adjust button pressed.
- The TMP alarm limits are ±200 mmHg (within the range of the technician set minimum TMP value to +500 mmHg) around the indicated TMP approximately 90 seconds after the UF rate is changed or the blood pump is turned on, off or rate changed, or the RESET button touched.
- The air and blood leak detector instrument alarm responses are disabled (except for the visual indicator).

For instruments with the Blood Pressure Monitor option:

- A manual blood pressure reading may be taken.
- The blood pressure schedule may be set, changed or manually stopped.

3.2.2 Dialyze Mode

3.2.2.1 Instrument status window displays

DIALYZE

3.2.2.2 Instrument action

- All alarms are functional. No alarm condition exists.
- The blood pump will operate.
- The venous line clamp is open.
- The UF rate is at the calculated value (from the PRESCRIBED TIME and TARGET UF), unless manually overridden or the calculated UF rate is less than the technician set minimum rate.
- The heparin pump will operate.

- The elapsed time is accumulated.
- While the blood pump is stopped and/or the Instrument is in bypass, the elapsed time is not accumulated.
- The main alarm lamp is off.
- The accumulated ultrafiltrate removed is displayed.
- The TMP alarm limits are set to ±35 mmHg (within the range of the technician set minimum TMP value to +500 mmHg) around the indicated pressure (reference pressure), approximately 90 seconds after the Dialyze Mode is started or the UF rate is changed, blood pump is turned on, the blood pump rate is changed, or the RESET button is touched.
- The TMP alarm limits are spread to a maximum 600 mmHg span (585 mmHg default) around the reference pressure for approximately 90 seconds when the blood pump or the UF rate is changed, then sets to a new ±35 mmHg window.
- The maximum high TMP alarm limit is +500 mmHg. The minimum low TMP is set by the technician.
- The SET LIMITS button may be used to manually set the TMP, arterial pressure, venous pressure alarm limit windows around the appropriate indicated pressure.
- The arterial pressure alarm limits spread to –300 and +600 mmHg, for approximately 10 seconds, when the blood pump is started or rate is changed, or the level adjust button pushed, or the RESET button touched.
- The venous pressure alarm limits spread to ±200 mmHg around the indicated venous pressure, for approximately 10 seconds, when the blood pump is started or rate is changed, or the level adjust button pushed, or the RESET button touched.
- The arterial and venous pressure alarm limits set to ±50 mmHg of the indicated value approximately 10 seconds after the blood pump is started or rate is changed, the level adjust button pushed, or the RESET button touched.
- The minimum low venous pressure alarm limit is approximately +10 mmHg.
- The main alarm lamp flashes and the audible alarm beeps 3 times approximately every 90 seconds, when the Instrument is in manual bypass or minimum UF, or the blood pump is off.
- The Event Timer is available.

For instruments with the Blood Pressure Monitor option:

- A manual blood pressure reading may be taken.
- The blood pressure schedule may be set, changed or manually stopped.

3.2.3 Alarm Mode

3.2.3.1 Instrument status window displays

ALARM

3.2.3.2 Instrument action

- An alarm indicator flashes to indicate the monitor that is in alarm.
- The main alarm lamp flashes at a rate of two times per second.
- Audio alarm sounds.
- The Event Timer is available.

Note

Refer to the Section 26, Alarms, in this manual for additional information.

3.3 FOLLOWING TREATMENT

In accordance with clinic procedures, the operator may choose one of several disinfection processes following a treatment, at the end of a shift, or at other times. For more on disinfection, see Section 9, Disinfection. The steps to Instrument Auto Off are dependent on the type of disinfection (if any) used prior to shutdown. For that reason, two disinfection modes are discussed here first, then the Auto Off Mode and the Soft Power Off Mode.

3.3.1 Heat Disinfection Mode

3.3.1.1 Instrument status window displays

HEAT CLEAN

3.3.1.2 Instrument action

- If the Heat Disinfection Mode is selected before the conductivity is less than 1 mS/cm, the fluid path will be rinsed until the conductivity is below 1 mS/cm then a timed rinse of approximately 4 minutes will be performed.
- The water is heated to above 84°C.
- The 85°C water is circulated through the fluid path for 15 to 60 minutes (value set by technician).
- Dialysate flow rate is automatically set to 500 mL/min.
- If dialyzer connector(s) is removed from the rinse block when the temperature is above 70°C, the Instrument will go into bypass after approximately 10 seconds. Once the dialyzer connectors are back on the rinse block, dialysate flow through the dialyzer circuit lines will resume.
- Main alarm lamp is off.
- Audio alarm is muted.
- The blood pump will not operate.
- The ELAPSED TIME display is on hold until the temperature reaches 85°C. Then the window displays the circulation time for the 85°C water.
- The heparin pump, dialysate flow rate, conductivity, temperature, prescribed time, target UF, TMP and UF rate functions cannot be accessed/changed.
- The UF rate is automatically set to 3.6 L/h.
- The operator may select AUTO OFF.

- The operator may manually start the Cool Down Mode. (See Warning in Section 3.3.2.)
- After completion of the circulating period, the Cool Down Mode is automatically started.
- The Event Timer is available.

For instruments with the Blood Pressure Monitor option:

- A manual blood pressure reading may be taken.

3.3.2 Cool Down Mode

3.3.2.1 Instrument status window displays

COOL DOWN

WARNING

Manually starting Cool Down will abort the Heat Disinfection Mode. If Heat Clean is cancelled before completion, the Instrument must not be used on a patient until it is properly disinfected. This can be done by completing another Heat Clean cycle, or by performing a Chemical Disinfect using any instrument-approved chemical EXCEPT bleach. Chemical Disinfect using bleach will not completely disinfect the Instrument once a Heat Clean cycle has been initiated and cancelled.

3.3.2.2 Instrument action

- Fresh water is circulated through the fluid pathway to cool down the circuit.
- Dialysate flow rate is automatically set to 800 mL/min or the maximum technician set dialysate flow rate, whichever is lower.
- When the temperature reaches the normal operating range, the Instrument automatically returns to the Rinse Mode.
- If dialyzer connector(s) is removed from the rinse block, the Instrument will go into bypass after approximately 10 seconds. Once the dialyzer connectors are back on the rinse block, dialysate flow through the dialyzer circuit lines will resume.
- Main alarm lamp is off.
- Audio alarm is muted.
- The blood pump will not operate.
- The ELAPSED TIME display indicates the time the 85°C water was circulated.

- The heparin pump, dialysate flow rate, conductivity, temperature, prescribed time, target UF, TMP and UF rate functions cannot be accessed/changed.
- The UF rate is 3.60 L/h.
- The Event Timer is available.

For instruments with the Blood Pressure Monitor option:

- A manual blood pressure reading may be taken.

3.3.2.3 After Heat Disinfection

- The cabinet fan will operate as required.
- At the end of Cool Down (default selection), the Instrument will enter the Rinse Mode once the temperature reaches 39.9°C.
- If Auto Off has been selected, the Instrument soft power is automatically initiated at the end of Heat Disinfection.

3.3.3 Chemical Mode

3.3.3.1 Instrument status window displays

CHEMICAL

3.3.3.2 Instrument action

- Automated fluid path rinse, chemical infusion, dwell and rinse appropriate for the selected chemical.
    - Prompts operator to make necessary concentrate line connections.
    - Prerinse of fluid path until conductivity <1.0 mS/cm, then timed rinse.
    - Prompts operator to make necessary concentrate and disinfect line connections.
    - Timed chemical infusion.
    - Timed recirculation and/or dwell (as applicable for chemical).
    - Prompts operator to make necessary concentrate and disinfect line connections.
    - Timed forced rinse.
    - Prompts operator to check for residual chemical.

- Main alarm lamp is off (except for operator prompts and error situations).
- Audio alarm is muted (except for operator prompts and error situations).
- The blood pump will not operate.
- The heparin pump, dialysate flow rate, conductivity, temperature, prescribed time, target UF, TMP and UF rate functions cannot be accessed/changed.
- The UF rate is automatically set to 3.6 L/h.
- ELAPSED TIME display indicates the elapsed time of each disinfection phase or HOLD as appropriate.
- The operator may select from technician set chemical list.
- Formaldehyde dilution is dependent upon technician setting.
- Auto soft power off during dwell for some chemicals.
- If dwell time is not complete when the Instrument is powered up, the operator is prompted about the remaining time and the Instrument automatically soft powers off.
- The operator may manually start the forced rinse.
- Forced rinse flow rate automatically set to technician set value.
- Forced rinse time dependent upon technician set residual chemical sample location, chemical and forced rinse flow rate.
- The Event Timer is available.

For instruments with the Blood Pressure Monitor option:

- A manual blood pressure reading may be taken.

3.3.4 Shut Down

3.3.4.1 Instrument status window displays

SHUTDOWN

3.3.4.2 Instrument action

- The blood pump is stopped.
- The venous line clamp is clamped.
- All pumps are stopped.
- UF flow meter is turned off.
- Audio alarm sounds.

- Main alarm lamp flashes.
- The operator is prompted to turn off the power.

3.3.5 Soft Power Off

3.3.5.1 Instrument status window displays

Display is off

3.3.5.2 Instrument action

- The front panel power switch is off.
- The cabinet fan will operate as required.
- The video display is off.
- The mains switch is on and the power cord is plugged in.

3.4 SERVICE MODES

See Section 18, Calibration / Adjustments, for detailed information.

3.4.1 Calibration Mode

This mode allows the Service Technician to set up the Instrument. It is not available to the operator.

3.4.2 Technician Mode

In this mode, all Technician Mode messages (labeled with a 01 number) appear at the top of the screen. This mode also allows the technician to skip self test.


Arena

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Arena

4. HYDRAULIC THEORY

4.1 OVERVIEW

The Arena Instrument is designed to heat incoming water to approximately human body temperature, mix the water with dialysate concentrate in physiologically correct proportions and infuse the dialysate through an artificial kidney to effect hemodialysis therapy. In doing this, it also accurately measures the amount of fluid entering and exiting the artificial kidney and can adjust these volumes to control the fluid removal from the patient. Operation of the hydraulic components is controlled by several microprocessors. Refer to Figures 4-1 and 4-2 for the location of components in the Instrument and to the standard hydraulics diagram (157-1278-587) at the end of this section for thier sequence in the flow path.

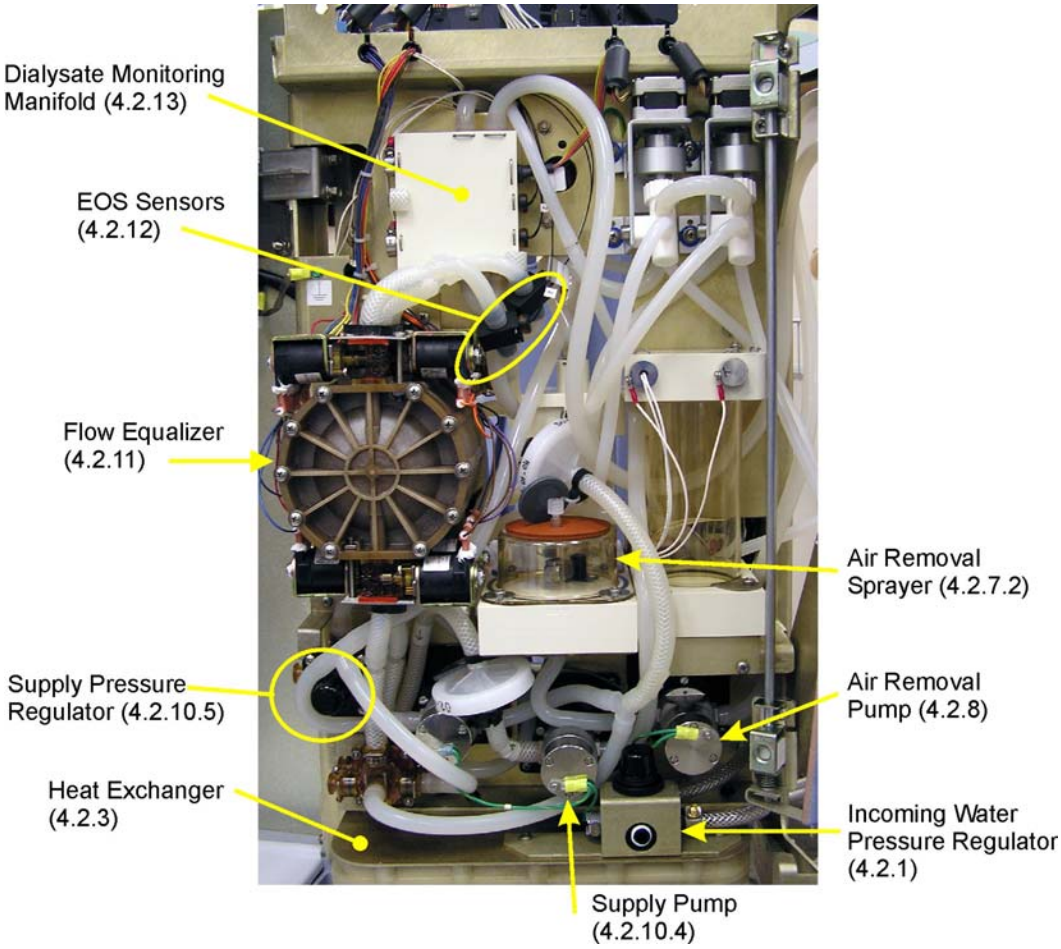


Figure 4-1. Standard Hydraulics Module, Front View

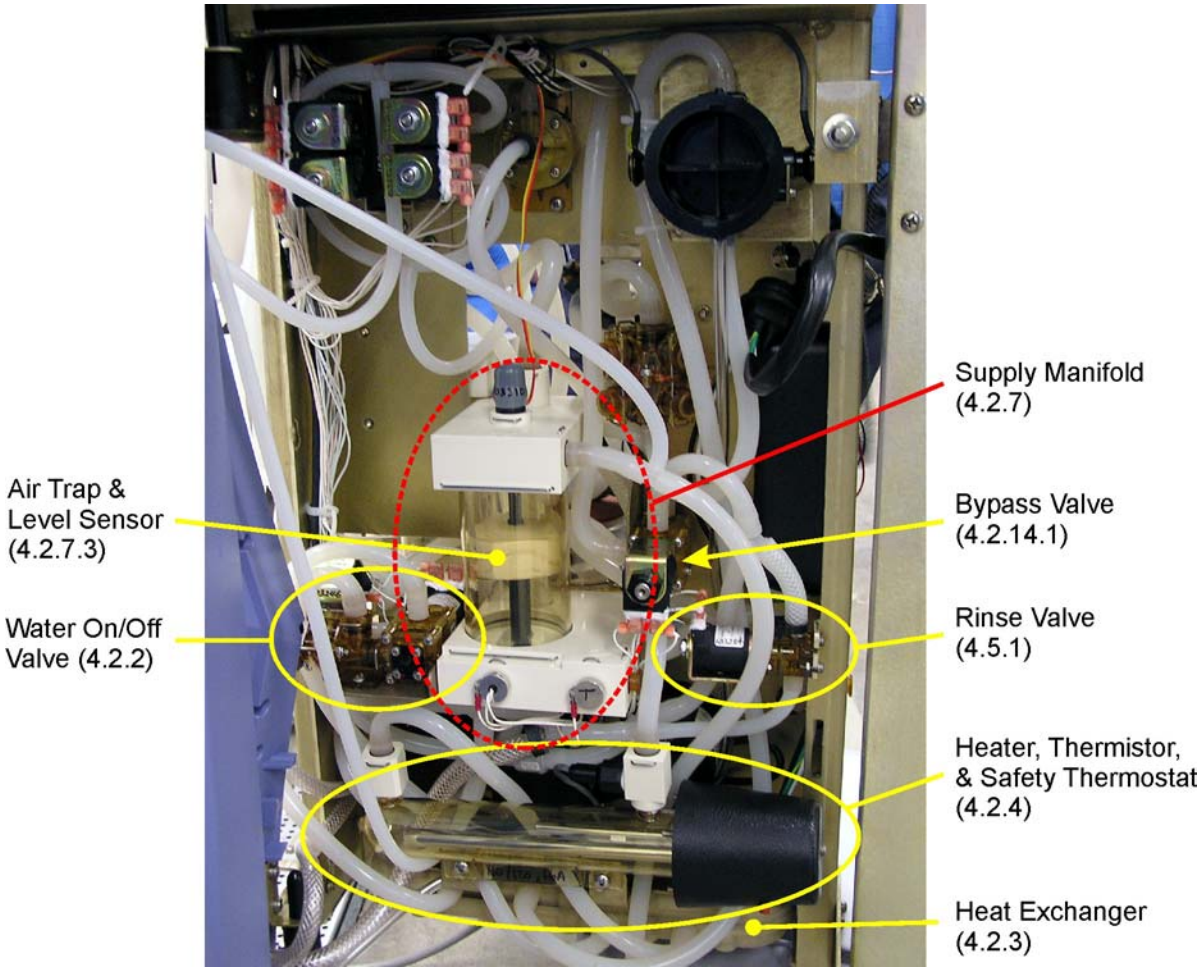


Figure 4-2. Standard Hydraulics Module, Rear View

4.2 DIALYSATE CIRCUIT

4.2.1 Incoming Water Pressure Regulator

The pressure of the incoming water is reduced and stabilized by the adjustable water pressure regulator to the factory-recommended level (see Section 18, Calibration Procedures).

Figure 4-3. Incoming Water Pressure Regulator

4.2.2 Water On/Off Valve

This valve is actuated through a coil using unregulated +24 VDC. When the power is off, the valve is closed preventing water from entering the Instrument. When power is on, the on/off valve operation is controlled by the supply manifold level sensor signal. During heat cleaning, the valve is closed. This valve can be monitored using the DS1 "Flow Control" LED on the I/O Hydraulics Power board (see Section 5, Electronic Theory).

4.2.3 Heat Exchanger

Incoming water flows through a hydraulic channel on one side of a stainless steel plate. On the other side of the plate, the spent dialysate flows in a countercurrent direction in an identical hydraulic channel before draining out of the Instrument.

Heat is transferred from the spent dialysate to the incoming water through the plate. This heat transfer preheats the incoming water, shortening dialysate warm up time. By reducing the time the heater is on, the heat exchanger saves energy.

The heat exchanger allows the Instrument to be used with a wider range of incoming water temperatures since this preheating of the incoming water reduces these variations.

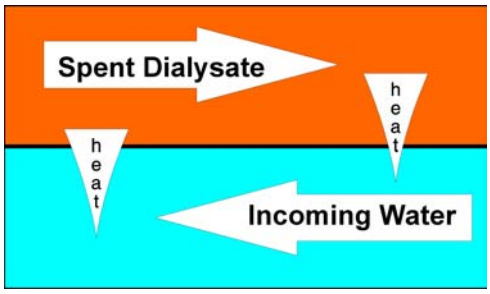


Figure 4-4. Heat Exchanger

4.2.4 Heater, Thermistor, Safety Thermostat

The water is heated to the desired temperature by a heater. On the output of the heater is a thermistor. The thermistor resistance changes in inverse proportion to temperature changes. The thermistor sends a signal to the UF-Proportioning Power board, which then turns the heater on or off to maintain or increase the temperature.

Next to the heater is a resettable thermostat, which prevents the heater from exceeding a temperature of approximately 107°C

(225°F). The thermostat turns off power to the heater to prevent damage in case of a runaway temperature circuit failure.

For testing purposes, the heater has a resistance of approximately 10-20 Ω when cold. The thermistor has a resistance of approximately 3 KΩ at 37 to 38°C and 5 KΩ at 25°C.

4.2.5 Concentrate Line Regulator(s) and Concentrate Central Delivery Systems (optional)

Concentrate Line Regulators are recommended when a central delivery system is used to feed concentrates into the Instrument.

Refer to Section 7, Dialysate Preparation, for more information.

4.2.6 Volumetric Proportioning System

The Instrument's volumetric proportioning system consists of fixed volume pumps for concentrates and a fixed volume metering device (Flow Equalizer) for dialysate. They are linked electronically through the Ultrafiltration Controller to provide a fixed ratio proportioning system.

Refer to Section 7, Dialysate Preparation, and Section 8, Ultrafiltration, for more information.

4.2.7 Supply Manifold

The supply manifold controls the incoming water flow, mixes the "A" dialysate concentrate component, removes the dissolved air from the water, and monitors the "A" concentrate and water conductivity. The supply manifold is composed of four components:

- "A" Mix Chamber and Air Gap
- Air Removal Sprayer
- Air Trap and Level Sensor
- "A" Conductivity Probe/Thermistor Set

This manifold also contains the connections for the air removal pump, and the "A" and "B" rinse fittings that connect through a common line to the supply manifold and draw rinse water from this source.

The "A" concentrate pump is described in Section 7, Dialysate Preparation.

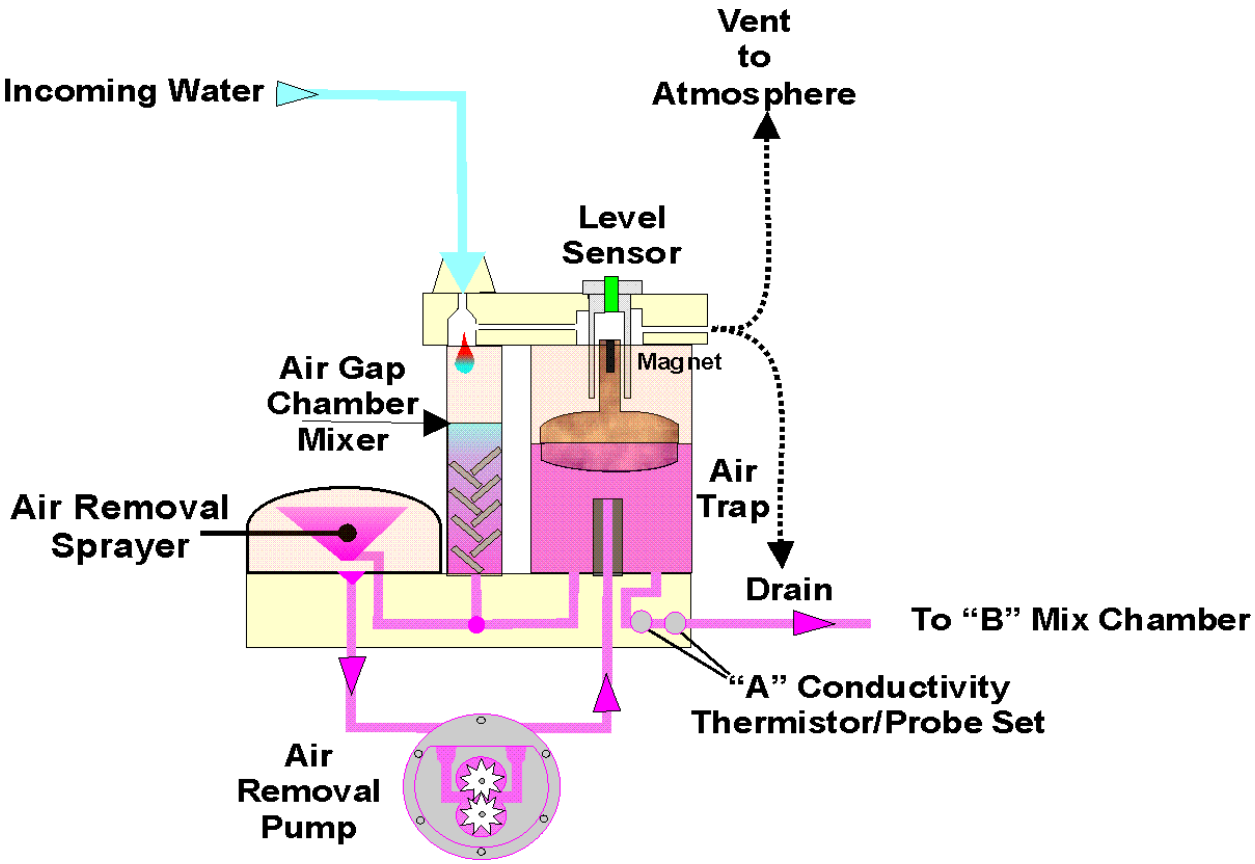


Figure 4-5. Supply Manifold

4.2.7.1 "A" Mix Chamber and Air Gap

As the name implies, the "A" mix chamber mixes the water and "A" concentrate into a uniform solution.

The air gap at the top of this chamber is at atmospheric pressure, which helps to limit proportioning errors. The air gap also acts as a barrier preventing back flow in the event of a drop in the incoming water pressure.

4.2.7.2 Air Removal Sprayer

The sprayer is part of the air removal system. Refer to Section 7, Dialysate Preparation, for more information.

4.2.7.3 Air Trap and Level Sensor

The air trap and level sensor control the flow of water into the hydraulic system by causing the water on/off valve to open when the level drops and by closing the valve when the level rises.

The level sensor consists of a float with magnet and a Hall-effect switch. When the water level float magnet is below the sensor, the condition indicates the need for more water, opening the incoming

water on/off valve. When the magnet is above the sensor, the condition indicates the air trap is full, closing the incoming water on/off valve.

In normal operation, as the supply pump draws solution from the air trap chamber to fill the flow equalizer, the liquid level in the chamber is lowered along with the float causing the water on/off valve to open so water again fills the chamber.

When the air trap level rises, the level sensor signal shuts off the water on/off valve. This cycle is repeated during every fill phase of the flow equalizer.

4.2.7.4 "A" Conductivity Probe/Thermistor Set

This is one of three conductivity probe sets. The other two are described in Section 4.2.10.3, "B" Conductivity Probe/Thermistor Set, and Section 4.2.13.1, Dialysate (Primary) Conductivity Probe/Thermistor Set.

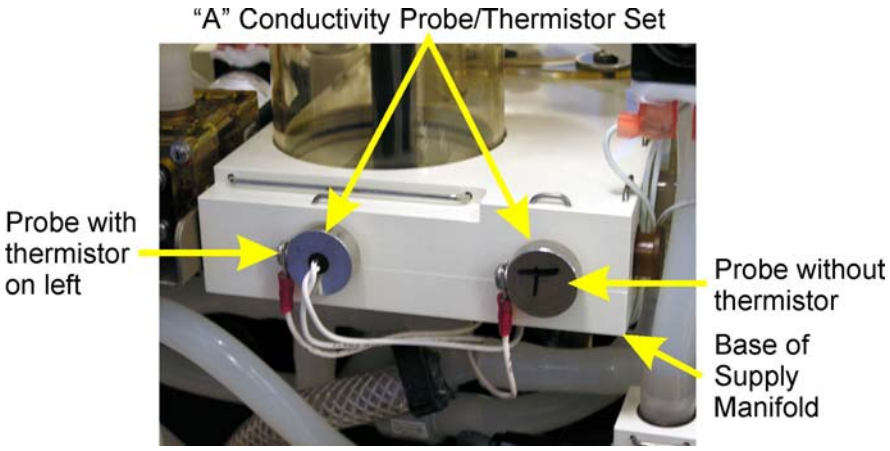


Figure 4-6. "A" Probe/Thermistor Set

Conductivity is used as a measure of the electrolyte composition of dialysate. The hardware for measuring conductivity is always a cell for measuring changing resistance as the amount of dissolved salt changes and a thermistor for measuring temperature changes. Electronic circuits are used to equate these changing resistances to the standard measuring conditions of a 1 cm cell at 25 Celsius. The information from these devices can be used to give us conductivity in the units of milliSiemens/cm (mS/cm) @ 25°C.

The "A" conductivity thermistor is not used to control or monitor the temperature of the dialysate. It is calibrated with the other thermistors during temperature calibration.

4.2.8 Air Removal System

The air removal system removes dissolved gases that are trapped in the water used to make up dialysate. The air removal system consists of the air removal sprayer, the air removal pump, and the vented air trap.

The air removal sprayer nozzle restricts the flow so that a partial vacuum of approximately 500 to 650 mmHg is created in the air removal sprayer chamber. The fluid that passes through the air removal sprayer is deflected into a conical spray pattern. By developing a spray pattern, a larger surface area is exposed to the 500 to 650 mmHg vacuum. The vacuum pulls the air out of the solution. Due to the large surface area of fluid exposed to the vacuum, the rate at which the air comes out of the water is increased, enhancing the air removal function.

The air removal pump (also known as the deaeration pump) runs at a constant speed of approximately 1500 mL/min for all flow rates, pulling the solution through the air removal sprayer nozzle.

The vented air trap provides an opening for air to leave the system. For more information, refer to Section 4.2.7 and Section 7, Dialysate Preparation.

4.2.9 "A" & "B" Rinse Fittings

The “A” and “B” rinse fittings are located on the right side panel of the Instrument. Both fittings are connected to a source of water in the supply manifold. This water is used to rinse the concentrate lines and concentrate pumps.

A proximity sensor built into each of the rinse fittings senses when the concentrate lines are attached. The rinse fittings are keyed so that the “A” concentrate line will not fit into the “B” concentrate fitting and vice versa. When the “B” concentrate line is not in use during acetate dialysis or during rinse, it is connected to its rinse fitting.

4.2.10 Supply Pump Recirculation Loop

The supply pump recirculation loop mixes the “B” concentrate, monitors the total conductivity, regulates the pressure, and pumps dialysate to the flow equalizer. This loop contains the inlet for the “B” concentrate pump, the "B" (bicarbonate) mix chamber, the

"B" conductivity probe, the supply pressure pump, and the supply pressure regulator. Figure 4-7 describes this loop.

The loop configuration helps to mix the bicarbonate concentrate by recirculating the solution through the "B" mix chamber. The loop also acts as a conduit for flow that is diverted by the supply pressure regulator at the end of each flow equalizer fill cycle.

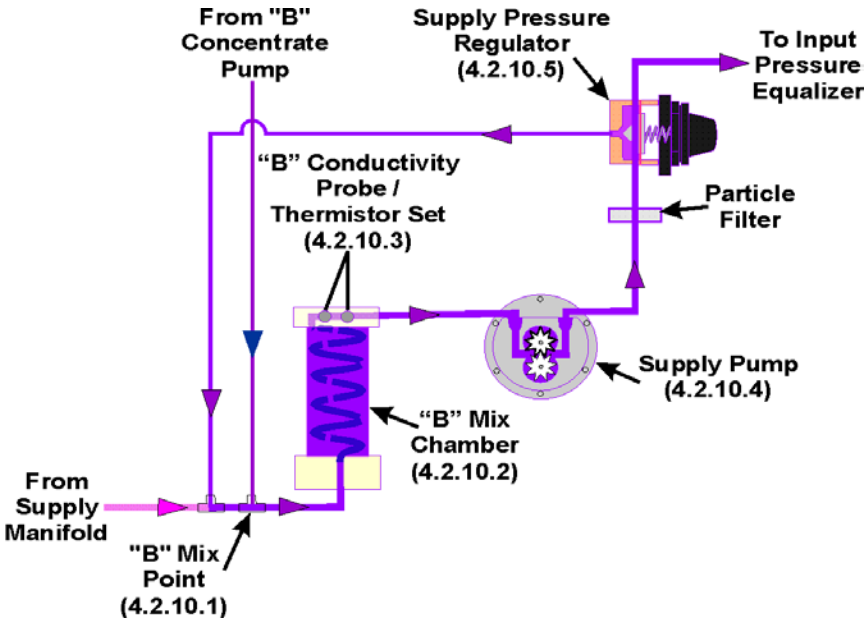


Figure 4-7. Supply Pump Recirculation Loop

4.2.10.1 "B" Mix Point

Bicarbonate concentrate enters the water-acid concentrate mixture at the "B" mix point.

4.2.10.2 "B" Mix Chamber

During hemodialysis therapy, the solution that enters the "B" mix chamber from the supply manifold contains water and acetate concentrate, or water and the acid and bicarbonate components of bicarbonate dialysate (depending on the concentrates selected). This chamber mixes the solution before it is monitored by the "B" conductivity probe.

4.2.10.3 "B" Conductivity Probe/Thermistor Set

This is one of three conductivity probe sets. The other two are described in Section 4.2.7.4, "A" Conductivity Probe/Thermistor Set, and Section 4.2.13.1, Dialysate (Primary) Conductivity Probe/Thermistor Set.

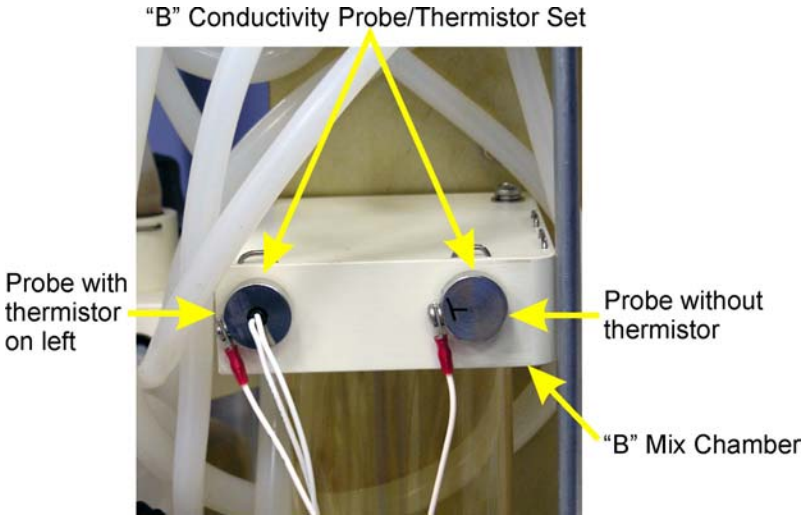


Figure 4-8. "B" Probe/Thermister Set

The second conductivity probe in the flow path is located at the outlet of the "B" mix chamber in the dialysate supply recirculation loop. The probe/thermistor set is identical to the "A" conductivity probe/thermistor set. In addition to compensating for temperature effect on the conductivity reading, the "B" thermistor is also the source of the temperature reading for the redundant high temperature alarm as well as fine-tuning the dialysate temperature control. Refer to Section 6, Temperature Control, for more information on temperature control.

The "B" probe monitors the total conductivity of the dialysate solution after both concentrates are mixed. The UF-Proportioning Controller board subtracts the "A" conductivity probe reading from the "B" conductivity probe reading and compares the difference to the expected result. In the acetate therapy mode, the result of this calculation should be zero and is used to recheck the "A" conductivity probe reading. When bicarbonate dialysate is used, the UF-Proportioning Controller board calculates whether the conductivity contribution of the "B" portion of the solution is acceptable for the type of bicarbonate concentrate used.

4.2.10.4 Supply Pump

The supply pump fills the flow equalizer with fluid. The supply pump pumps at a rate slightly higher than the dialysate flow rate set by the operator. This extra flow ensures an adequate supply of solution to fill the flow equalizer. For more information on the speed control of the supply pump, refer to Section 7, Dialysate Preparation.

4.2.10.5 Supply Pressure Regulator

The supply pressure regulator controls the peak input pressure to the "pre" side of the input pressure equalizer. When the flow equalizer cavity is filled, the pressure in the pressure regulator increases to its maximum value (16 psi ±1), overcoming the spring force of the regulator spring allowing the dialysate to recirculate back to the “B” mix chamber. The Supply Pressure Regulator is equivalent to an adjustable pressure relief valve. See also Section 8, Ultrafiltration.

4.2.11 Input Pressure Equalizer, Flow Equalizer, and Output Pressure Equalizer

Refer to Section 8, Ultrafiltration, for a detailed description of these components.

4.2.12 End-of-Stroke Sensors

The end-of-stroke (EOS) sensors are infrared optical devices located in the flow path after the Flow Equalizer and before the Output Pressure Equalizer. These sensors verify when the Flow Equalizer compartments have reached the end of the fill cycle. When the compartments are full, the sensor sends a signal to the UF-Proportioning Power board. The EOS sensors are used to minimize the end-of-stroke time of the Flow Equalizer by controlling the flow rate of the supply pump via feedback from the sensors.

The Instruments that have temperature-dependent EOS sensors, work with self-heating thermistors. The temperature of these thermistors will rise when the flow through them stops.

The Instrument may have optical EOS sensors like the one shown in Figure 4-9. (The diagrams in this section show the optical sensor.) The main components are two small PCBs, one on each side of the assembly, and one diaphragm right in the middle of the assembly. One PCB has the circuitry for the LED, and the other for the Detector. On the body of the assembly, the orientation of the diaphragm is indicated by a raised alignment symbol.

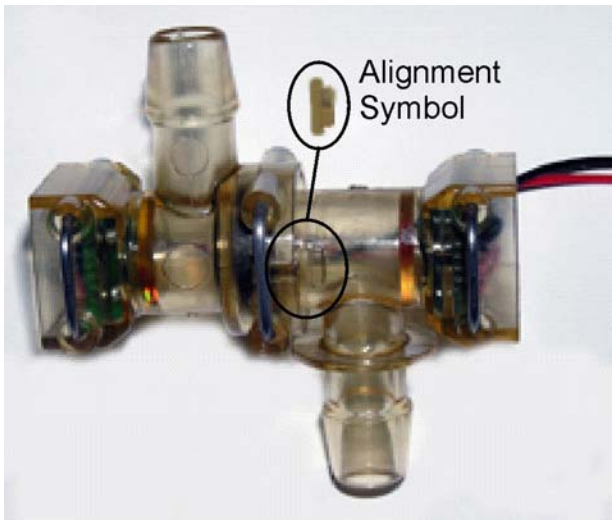


Figure 4-9. Optical Sensor Assembly

The diaphragm has four flaps that will open under a pressure of 0.5 PSI, allowing the light from the LED to go across the assembly and reach the Detector (see Figure 4-10). This will indicate that dialysate is flowing. When the flow stops, the diaphragm will close, blocking the light from the LED, which indicates that the flow stopped.

A green LED on the Detector PCB will turn on when the Detector does not get any light.

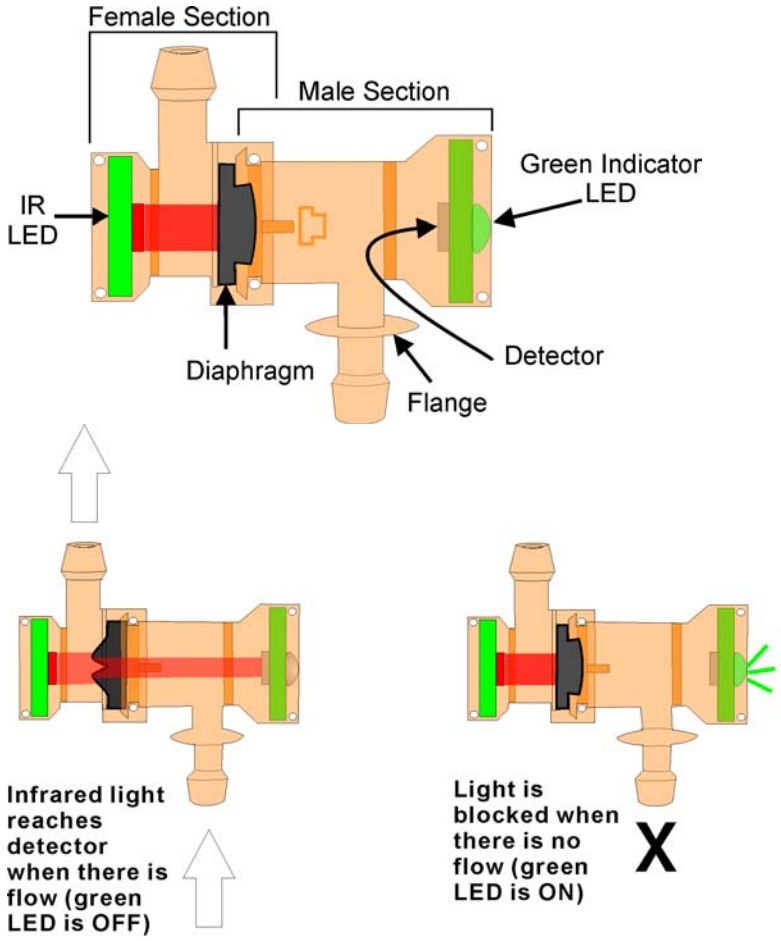


Figure 4-10. Optical/Diaphragm Sensors for EOS

4.2.13 Dialysate Monitoring Manifold

The purpose of this assembly is to house the components to monitor the dialysate temperature, conductivity and pressure. This manifold contains:

- The dialysate (primary) conductivity probe/thermistor set
- The dialysate pressure transducer
- The bypass valve flow sensor

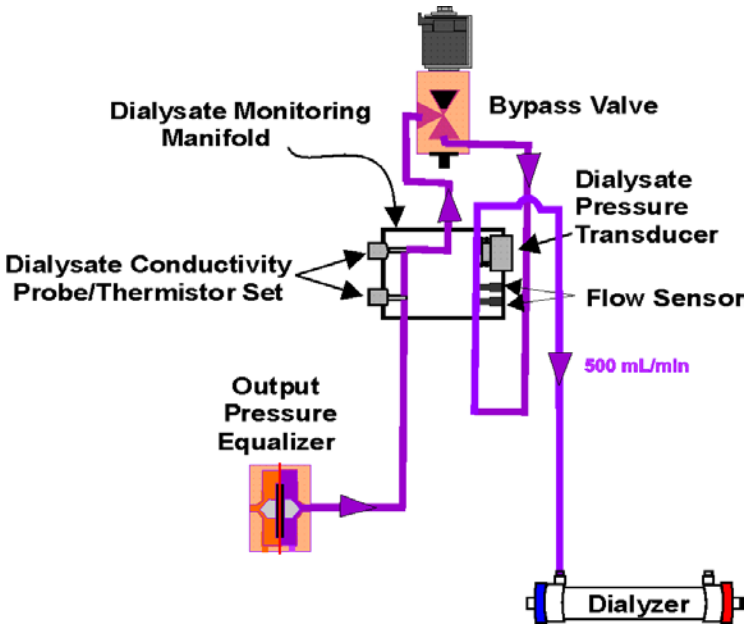


Figure 4-11. Dialysate Monitoring Manifold

4.2.13.1 Dialysate (Primary) Conductivity Probe/Thermistor Set

This is one of three conductivity probe sets. The other two are described in Section 4.2.7.4, "A" Conductivity Probe/Thermistor Set, and Section 4.2.10.3, "B" Conductivity Probe/Thermistor Set.

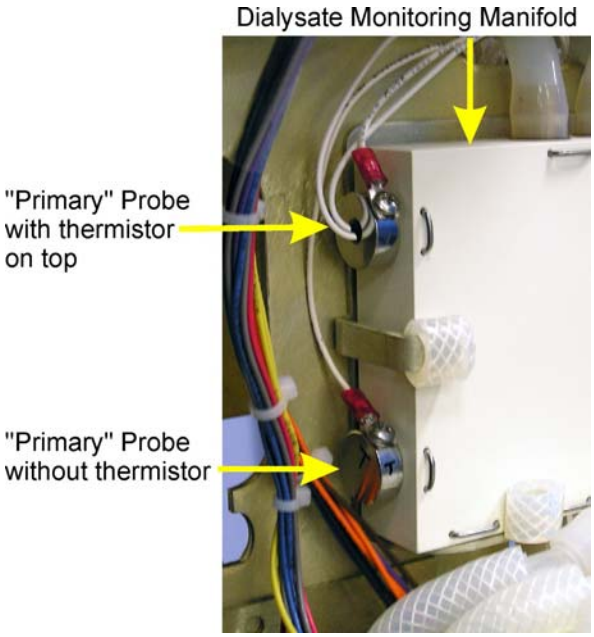


Figure 4-12. "Primary" Probe /Thermistor Set

The third conductivity probe/thermistor set is located in the Dialysate Monitoring Manifold at the outlet of the output pressure

equalizer. This probe set is identical to the other conductivity probe sets. It measures the total conductivity of the dialysate before it enters the artificial kidney. This temperature-compensated conductivity value is displayed in the CONDUCTIVITY window. The primary conductivity alarm circuit also uses the signal from this probe.

As mentioned previously, a thermistor is built into one of the electrodes. This thermistor supplies information for the temperature display and the primary high and low temperature alarm limits. For more information on temperature monitoring, refer to Section 6, Temperature Control.

4.2.13.2 Dialysate Pressure Transducer

This pressure transducer senses the dialysate pressure and changes the pressure reading into an analog electrical signal proportional to pressure. This signal is used for the transmembrane pressure display and alarms.

4.2.14 Dialysate Bypass Valve and Sensor

4.2.14.1 Bypass Valve

The bypass valve protects the patient in the event of a temperature or conductivity alarm by diverting unacceptable dialysate away from the dialyzer. The diverter is a +24 VDC three-way solenoid valve, controlled by the I/O Hydraulics Power board. During a dialysate temperature or conductivity alarm, an electronic signal causes the bypass valve to close the fluid path leading to the dialyzer and shunt the dialysate to the drain.

On the I/O Hydraulics Power Board, LED DS6 indicates Bypass (off) or Flow (on). See Figure 4-13 for location.

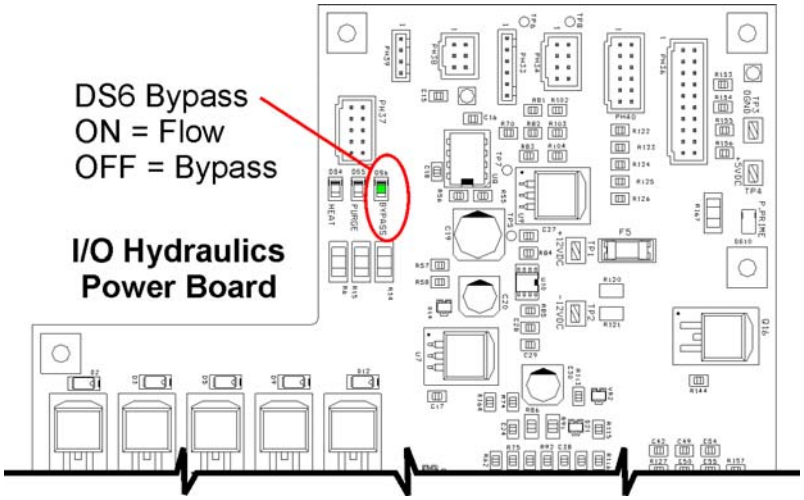


Figure 4-13. Bypass/Flow LED

While in Rinse Mode, the Instrument will automatically go into Bypass Mode periodically.

There is also a manual Bypass Mode that permits the operator to put the Instrument in bypass when a dialyzer is connected or sequential ultrafiltration therapy is performed. This manual Bypass Mode is activated via the Bypass switch located on the Membrane Switch Panel.

4.2.14.2 Bypass Valve Flow Sensor

A temperature-dependent flow sensor connected (see Figure 4-11) to the dialysate monitoring manifold after the bypass valve is used to monitor dialysate flow. When the Instrument is in bypass, the bypass valve diverts the dialysate flow away from the dialyzer; therefore this sensor verifies the correct functioning of the bypass valve by detecting that no flow is going through the sensor. The Instrument generates a shutdown alarm in the event of a bypass valve failure.

The signal from the Flow Sensor is also used to indicate dialysate flow or bypass on the touchscreen display. Refer to Section 4.2.12 for more information on the sensor assembly.

4.2.15 Rinse Block

When the Instrument is not being used for a patient treatment and a dialyzer is not in use, the dialysate lines are attached to a rinse block. The rinse block has proximity sensors that are used to determine the placement of the dialyzer connectors and are used as interlocks for mode changes.

4.2.16 Dialysate Sample Ports

The sample ports (pre- and postdialyzer) are provided as an opening for the operator to obtain a sample of the dialysate to test for conductivity or residual disinfectant.

4.3 ULTRAFILTRATION SYSTEM

The ultrafiltration (UF) system allows the operator to remove a precise amount of fluid from a patient in a controlled manner. By controlling exactly how much dialysate is going to and returning from the dialyzer, accurate fluid removal is achieved.

The main components of the UF system are (as they appear in the flow path):

- Supply Pump
- 150µ Particle Filter

- Supply Pressure Regulator
- Input Pressure Equalizer
- Flow Equalizer
- Output Pressure Equalizer
- Dialyzer Connectors and Dialyzer
- Check Valve
- Dialysate Pressure Pump
- Flow Restrictor
- UF Removal Regulator
- UF Flow Meter

Refer to Section 8, Ultrafiltration Control, for more information on the UF System.

4.4 BLOOD LEAK DETECTOR

Spent dialysate expelled from the flow equalizer passes through and is monitored for the presence of blood in the blood leak detector. There is a light source and a photocell which monitors the light transmitted through the solution present in the cavity. If blood leaks through the dialyzer membrane, the blood passing through the blood leak detector will absorb a portion of the light, preventing it from reaching the photocell. The dimmed light then sets off a blood leak alarm and protects the patient by stopping the blood pump, clamping the venous line, and warning the operator. For more information, refer to Section 14, Blood Leak Detector.

4.5 OTHER COMPONENTS

4.5.1 Rinse Valve

The rinse valve (also called the dialysate pressure relief valve) connects to the fluid path immediately after the flow sensor on the downstream side of the dialyzer. When the Instrument is in the Rinse Mode, the electronics control the UF flow meter to meter 3.6 L/h of fluid out of the flow path. Fluid must be added to the system to prevent a vacuum from being built up in the flow path. The rinse valve allows fluid from the drain line to replace the volume removed by the UF flow meter.

The rinse valve is open in the Rinse and Prime Modes, in Self Test (except UF test) and in the Calibration Mode when the UF Flow Meter is being calibrated. Therefore, when the dialyzer connectors are not connected to the Instrument, the rinse valve must be closed.

4.5.2 Heat Disinfection Recirculation Valve

The heat disinfection recirculation valve diverts the effluent water back into the input side of the heater (with the water on/off closed) in order to heat the water to above 84°C and maintain that fluid path temperature for the time set by the service technician. For more information, refer to Section 9, Disinfection.

4.5.3 Citric Acid Valve Manifold (optional)

This manifold is part of the Citric Acid option. It consists of a normally-closed two-way valve, which opens during the Citric Acid Heat Clean Mode if the dialyzer connectors are on the rinse block and citric acid is to be infused.

If the dialyzer connectors are removed from the rinse block during citric acid infusion, the citric acid valve will close, citric acid infusion will stop, and the message PLACE DIALYZER LINE ON RINSE BLOCK will be displayed.

For more information on the Citric Acid option, refer to Section 2, Physical Description, and Section 9, Disinfection.

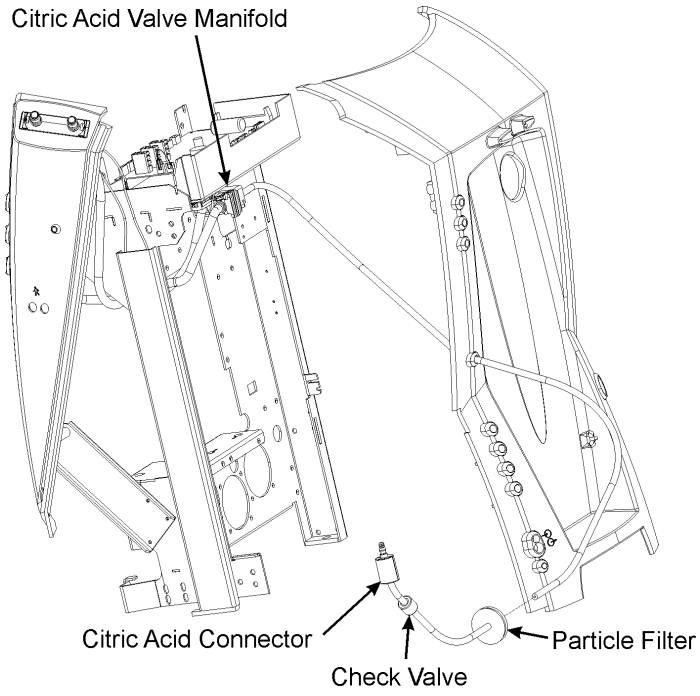


Figure 4-14. Citric Acid Option Hardware


Arena

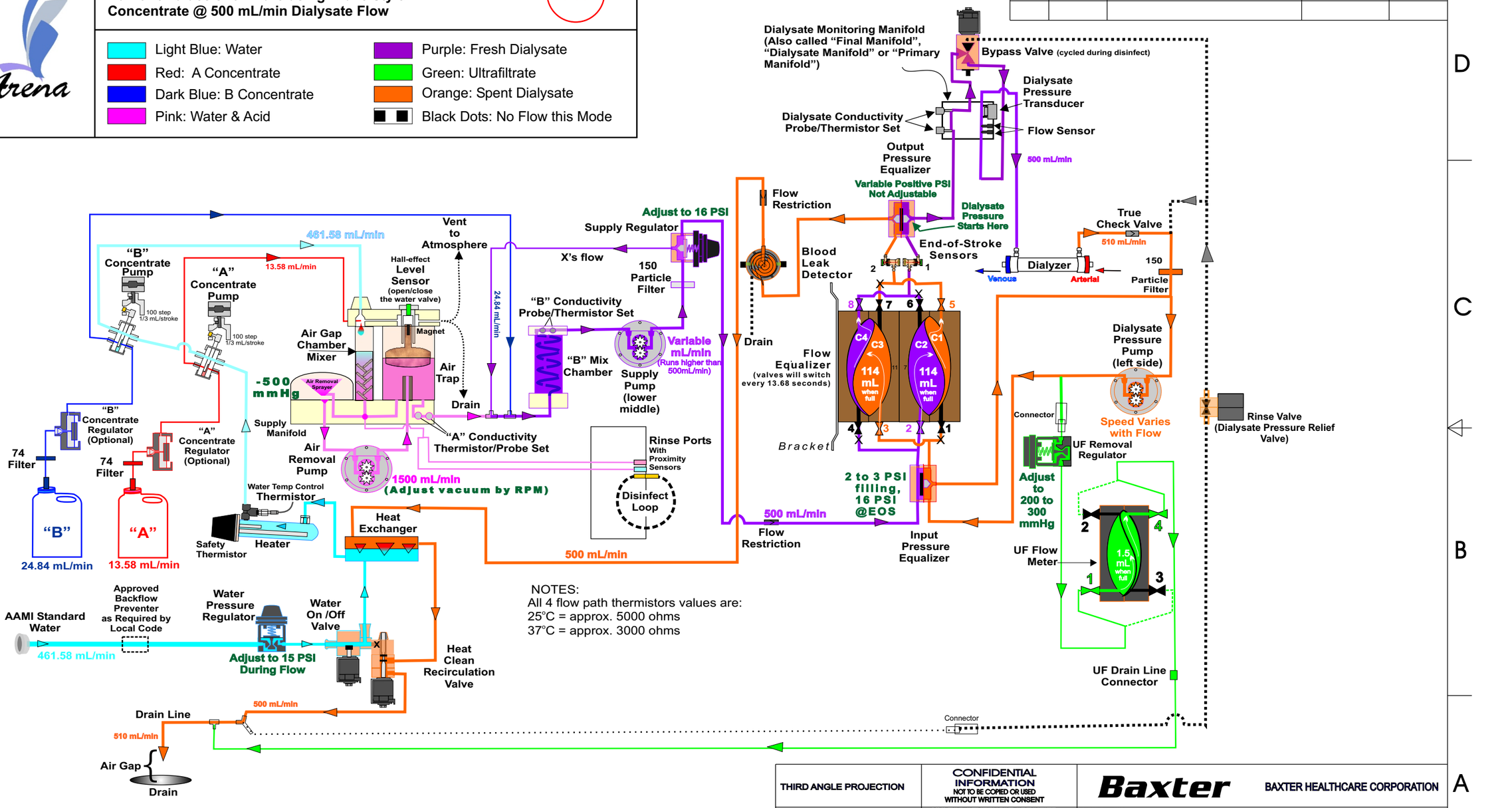
REV	ECO #	DESCRIPTION	APPROVED	DATE

Dialyze Mode

Numeric values shown are using Drake Style Concentrate @ 500 mL/min Dialysate Flow

36.83X

- Light Blue: Water
- Red: A Concentrate
- Dark Blue: B Concentrate
- Pink: Water & Acid
- Purple: Fresh Dialysate
- Green: Ultrafiltrate
- Orange: Spent Dialysate
- Black Dots: No Flow this Mode



NOTES:
All 4 flow path thermistors values are:
25°C = approx. 5000 ohms
37°C = approx. 3000 ohms

THIRD ANGLE PROJECTION	CONFIDENTIAL INFORMATION NOT TO BE COPIED OR USED WITHOUT WRITTEN CONSENT	Baxter — BAXTER HEALTHCARE CORPORATION
	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. TOLERANCES ARE: DECIMALS .XX ± .01 .XXX ± .005 ANGLES ± .5^	DESCRIPTION: Arena Standard Hydraulics Flow Diagram
	SURFACE FINISH: 63	MATERIAL / FINISH / SPECIFICATIONS
	DO NOT SCALE DRAWING BREAK ALL SHARP CORNERS .005/.010 CHAMFER/RADIUS	DWG No. B ▫ 157-1278-587 REV A
		DRAFTER L. Pittman DATE 1-8-04
		SCALE None SHEET 1 OF 1
		CorelDRAW FILE

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Arena

5. ELECTRONIC SYSTEM ARCHITECTURE

5.1 OVERVIEW

This section describes the electronic system architecture of the Arena Dialysis Delivery System. Some details may vary for individual Instruments according to the options installed. While reviewing this section it is recommended that you refer to the Input/Output Diagrams when available that correspond to the specific circuits being described.

Refer to the Interconnect Block Diagram in Figure 5-1 (next page) for an overview of the electronic architecture and also to the Interconnect Diagram at the end of this section.

Two letters identify most of the printed circuit boards. All the connectors on the boards will be identified with these letters plus a number.

Table 5-1. Electronic Board Identifiers

Printed Circuit Board	Location	Identifier
Blood Pump Controller	Card Cage, Slot 5*	PB
I/O Controller	Card Cage, Slot 6	PD
UF-Proportioning Controller	Card Cage, Slot 7*	PC
Blood Pump Power	Above Blood Pump(s)	PF
UF-Proportioning Power	Hydraulics Module	PG
I/O Hydraulics Power	Hydraulics Module	PH
I/O Electronics Power	Lower Chassis	PI
Venous Line Clamp Driver	Lower Chassis	PK

Notes

**Blood Pump and UF-Proportioning Controller boards are physically identical. The type of controller they become is determined by the position of a jumper on the board and software on the EEPROM. Refer to Sections 5.4.4 and 5.4.6.*

Thin lines in Figure 5-1 are components; thick lines are printed circuit boards.

The architecture is described starting with the input power and continuing as it is distributed throughout the Instrument. It also follows the flow of the water and concentrates as well as the blood flow.

Table 5-12 at the end of this section, shows information on all fuses used in the Instrument.

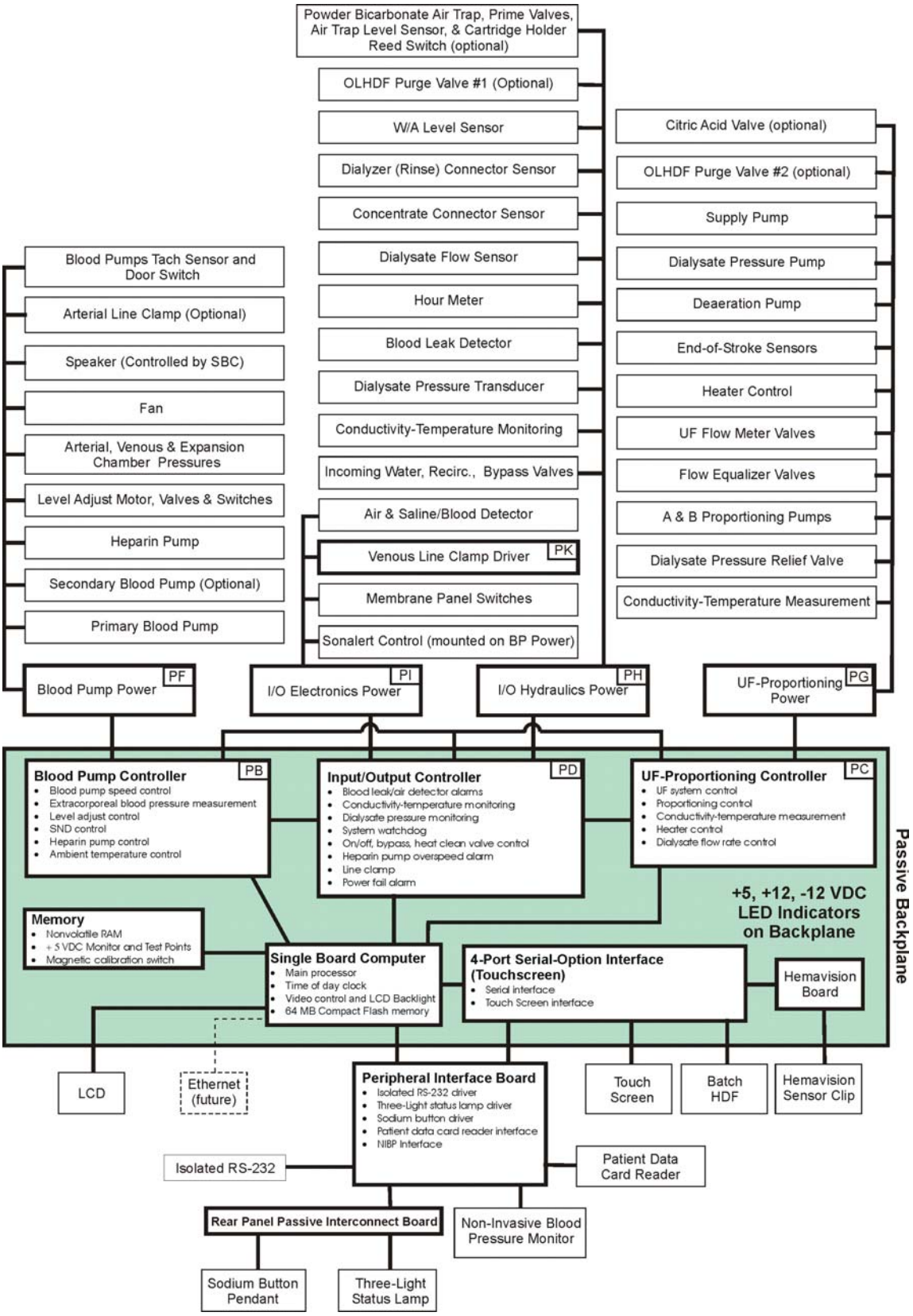

Figure 5-1. Interconnect Block Diagram

5.2 SOFT AND HARD POWER ON/OFF

The power line circuit breaker/mains switch is used to Hard Power On and Off the Instrument. When this switch is in the Off position the Instrument is Hard Powered Off and all power is removed from the Instrument; however, the Instrument remains grounded as long as it is connected to a properly grounded AC power Outlet.

Table 5-2. Hard and Soft Power On/Off

Hard Power	Soft Power	Systems Available
OFF	OFF	None
OFF	Cannot be ON	None
ON	OFF	Electronics are powered on, fan can run as needed Heater, motors, valves, video displays are all off.
ON	ON	All systems are operational.

Once the Instrument has been hard powered on, the Instrument is turned on or off with the soft power on/off switch on the membrane switch panel (see Section 2). The soft power on/off switch does not break the mains power to the Instrument, therefore the electronics are powered on.

5.3 POWER SYSTEM

5.3.1 Power Requirements

The Instrument requires a nominal input voltage of 110, 120, 230 or 240 VAC. Input voltage must be within ±10% of the rated nominal value.

Typical input current in a 120 VAC Instrument is approximately 3 A when the heater is Off. When the heater is On, the typical input current is about 15 A. Instruments will draw currents that are inversely proportional to the input voltages.

5.3.2 Input Power Distribution

Refer to Figure 5-2 for a block diagram of the Input Power distribution, and Figure 5-3 to physically locate the components that are part of it.

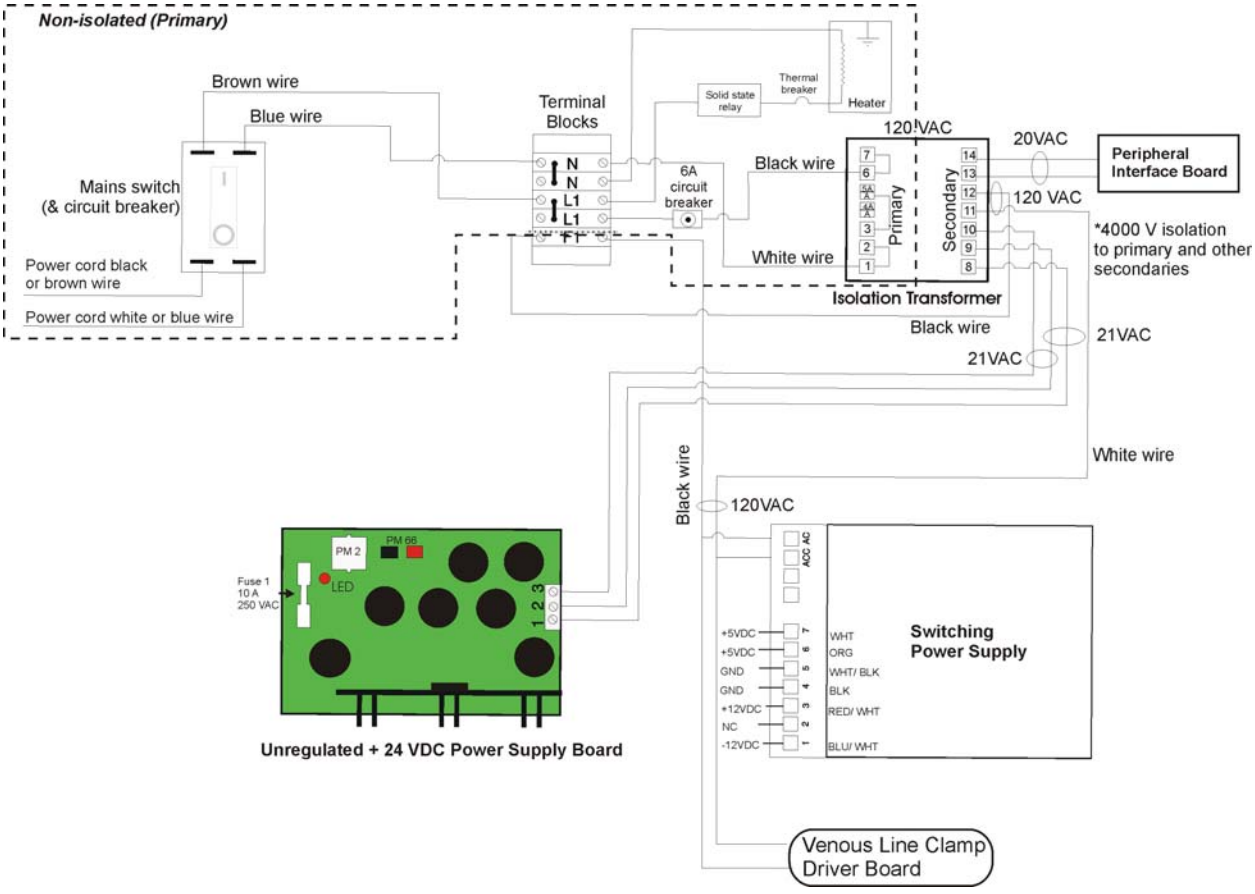

Figure 5-2. Input Power Distribution

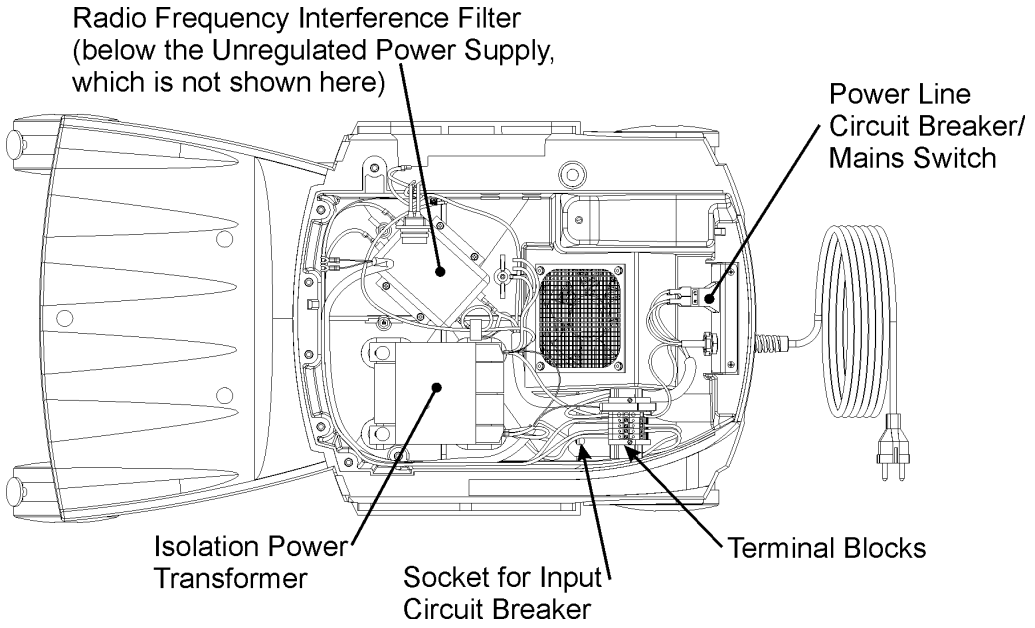

Figure 5-3. Power Distribution Components

Input power distribution is accomplished by the following major components:

- **Power Line Circuit Breaker/Mains Switch.** This switch is used to hard power On and Off the Instrument, as well as a resettable automatic thermal circuit breaker. All input current passes through this power line circuit breaker. In the event of excessive current draw by the Instrument, the circuit breaker will trip thus protecting the Arena. Both sides of the power line are broken by the circuit breaker.

  The power line circuit breaker/mains switch supplies non-isolated power directly to two loads: the dialysate heater and the power transformer.

  The non-isolated power to the dialysate heater circuit is switched by means of a solid state relay.

- **Radio Frequency Interference Filter.** This filter reduces electrical noise in the power line.

- **Terminal Blocks.** They are located in the base of the Instrument. They interconnect the wires from the Mains Switch to the Isolation Transformer and Heater. There is a block that contains the Terminal Block Fuse F1.

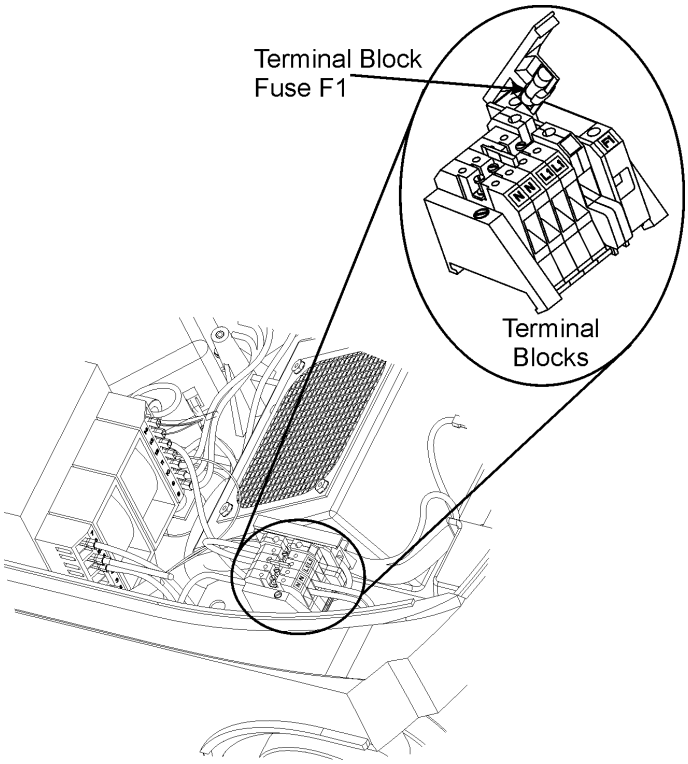

Figure 5-4. Terminal Block and Fuse F1

- **Terminal Block Fuse F1.** This fuse is located in the Terminal Block. It is a 2 A, 250 VAC replaceable fuse that protects the transformer from a short-circuit in the output 120 VAC line. This line goes from the transformer (connector #12) to the Switching Power Supply, and the Venous Line Clamp Driver Board.

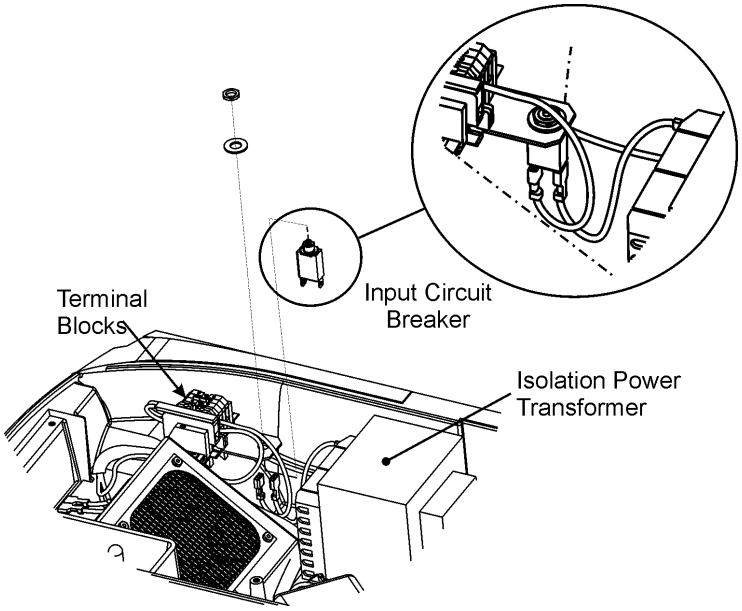

Figure 5-5. Input Circuit Breaker and Isolation Power Transformer

- **Input Circuit Breaker CB2**. This is a 6 amp push-button input circuit breaker in series with the power transformer primary winding that protects the input 120 VAC line to the Isolation Power Transformer.
- **Isolation Power Transformer.** With the exception of the heater, this transformer isolates the electronics from the input line. There are four optional input voltages: 110, 120, 230, and 240 VAC. All options use the same transformer with the primary coils wired in a different way. Figure 5-6 shows how two options are physically connected, and Figure 5-7 shows a schematic diagram with all options.

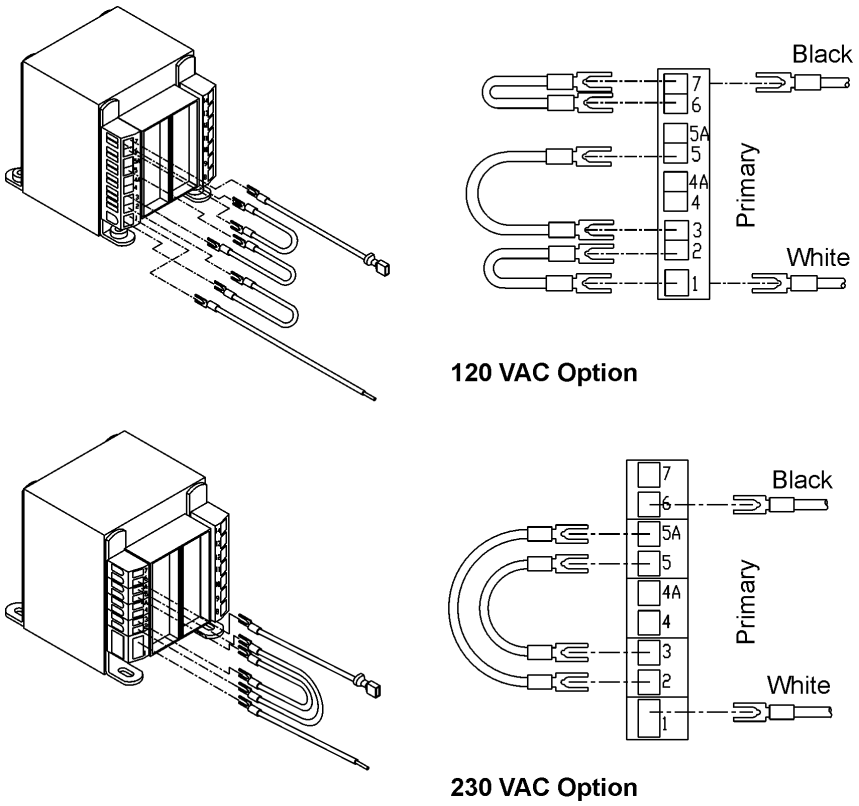

Figure 5-6. Input (Primary) 120 and 230 VAC Configurations

The transformer has three isolated secondary windings, with output voltages equal for all options:

- 21 VAC, this is actually a winding with a middle tap, so there are two 21 VAC lines and one common line that supply power to the Unregulated Power Supply. A voltage reading between terminals 8 and 10 will be of about 42 VAC.
- 120 VAC supplies power to the Switching Power Supply and the Venous Line Clamp Driver Board.
- 20 VAC, supplies power to the Peripheral Interface Board.

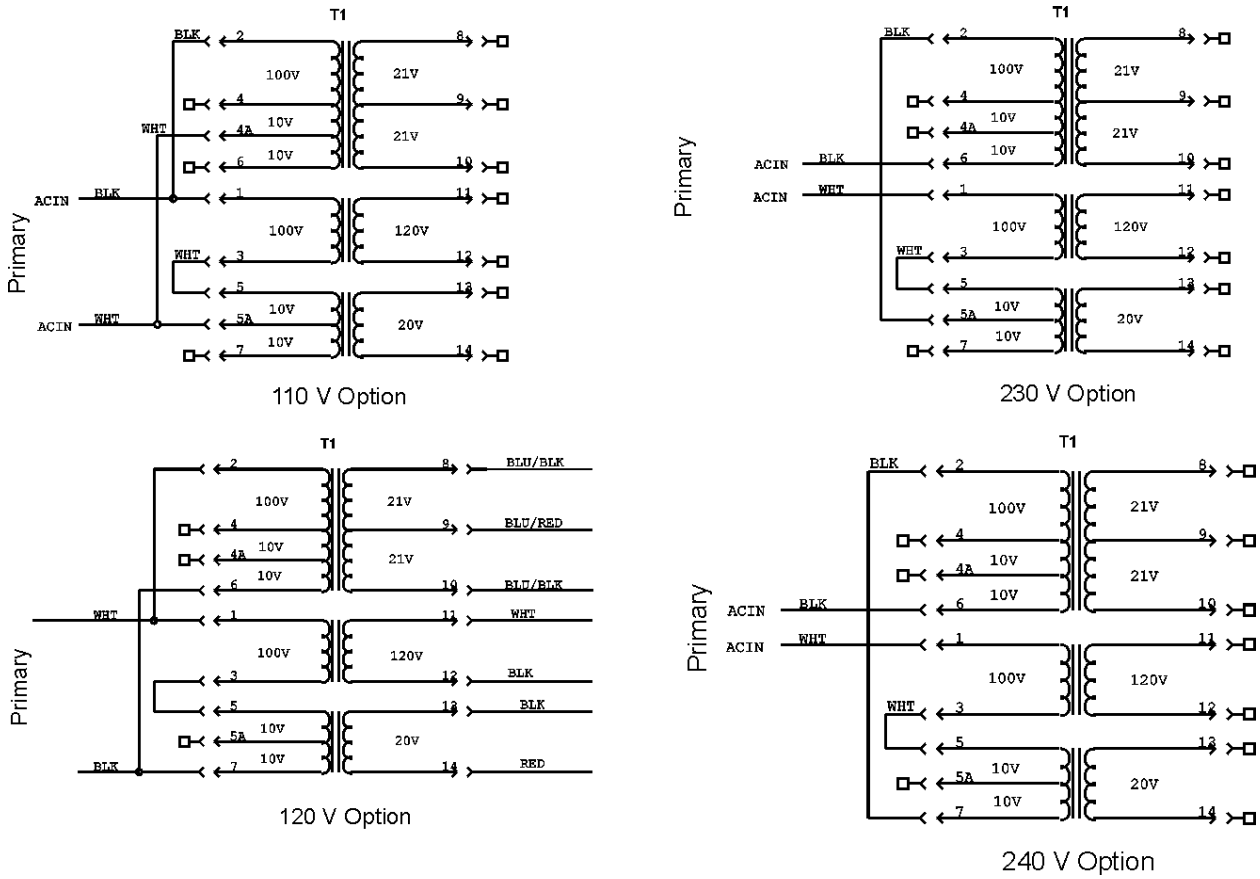

Figure 5-7. Isolation Power Transformer Options

- **+24 VDC Unregulated Power Supply (+29.5 +/- 3 VDC)**
  This power supply rectifies and filters the 21 VAC from the Isolation Power Transformer into unregulated nominal +24 VDC. The expected voltage reading from this power supply is **+29.5 ± 3 VDC.** This board has a 10 amp 250 VAC fuse, and an LED that turns on to indicate that power is being applied to the Power Supply.

  The unregulated power supply provides power directly to the following boards, see Figure 5-8.

  - Blood Pump Power Board
  - UF-Proportioning Power Board
  - I/O Electronics Power Board
  - I/O Hydraulics Power Board
  - Peripheral Interface Board
  - Optional HDF Board

  These boards, in turn, selectively feed this unregulated nominal +24 VDC to motors, valves, and pumps.

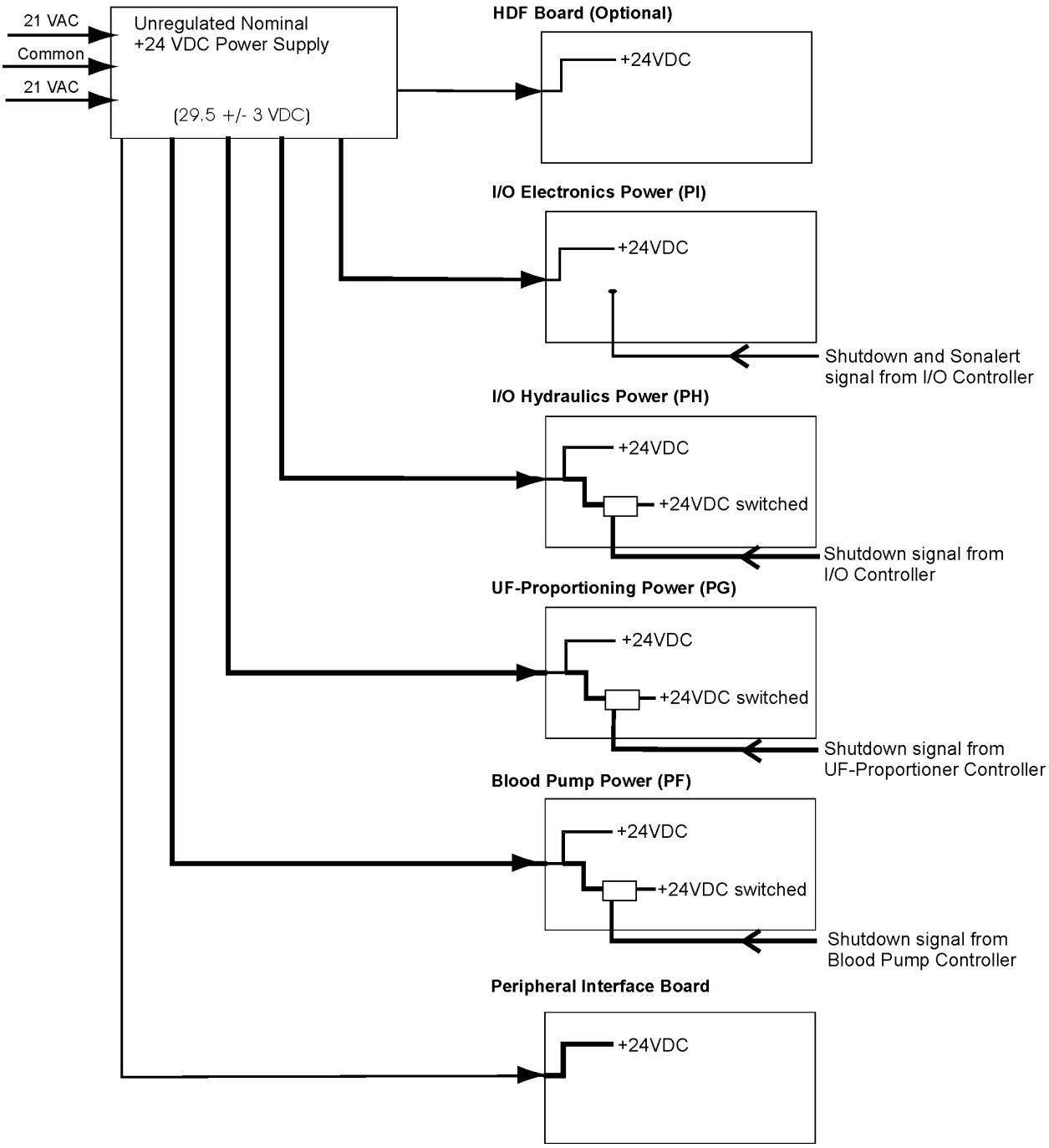

Figure 5-8. Unregulated Nominal +24 VDC Power Distribution

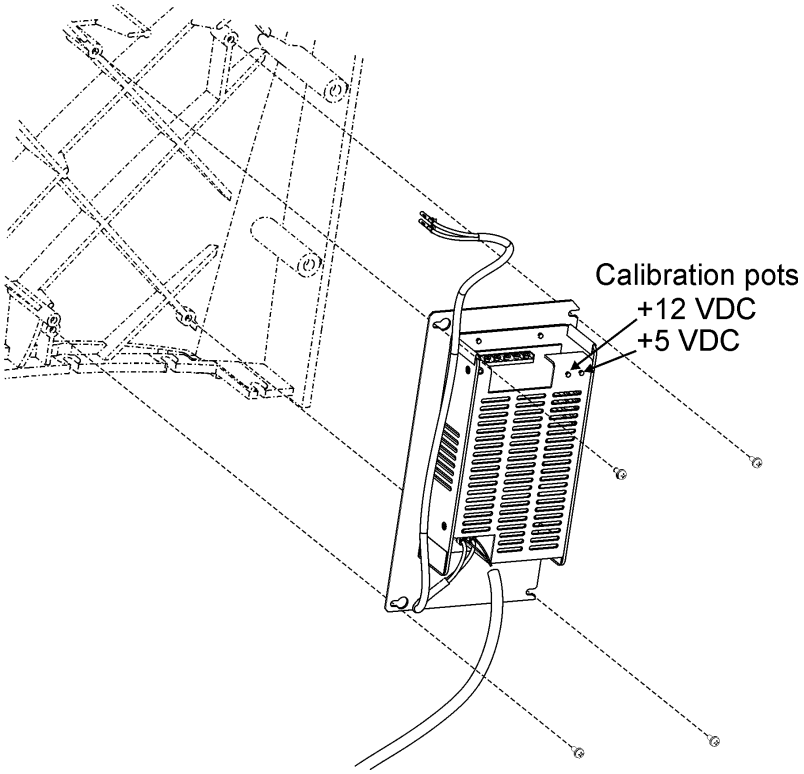

Figure 5-9. Switching Power Supply

- **Switching Power Supply.** This power supply rectifies and filters the 120 VAC from the Isolation Power Transformer. This board has an internal 3A/250 VAC fuse.

  This power supply provides +5 VDC and ground for the digital circuits, and +12 and -12 VDC and ground for the analog signal conditioning circuits in all boards. Only the +5 and +12 VDC can be calibrated. (See Figure 5-9 for potentiometer locations.) The +5 VDC should be calibrated to between +5.00 and +5.05 VDC. These voltages are fed directly to the following boards (see Figure 5-10).
  - Passive Backplane
  - Peripheral Interface Board (this board distributes power to the NIBP and PDC reader, see Figure 5-10)
  - LCD

  You may monitor these voltages easily using the UF-Proportioning Power Board test points.

Note

The adjusting pots on the Switching Power Supply are extremely sensitive, so make sure to turn them only very little every time.

The Passive Backplane filters and distributes the +5, +12 and -12 VDC to all boards in the Card Cage. These boards in turn distribute power to the Power Boards:

- Blood Pump Power Board
- UF-Proportioning Power Board
- I/O Electronics Power Board
- I/O Hydraulics Power Board

The I/O Controller board monitors the +5 VDC power supply so that if it suddenly changes to a level that incapacitates the digital logic circuits, then the watchdog circuit on this board times out and forces a system shutdown.

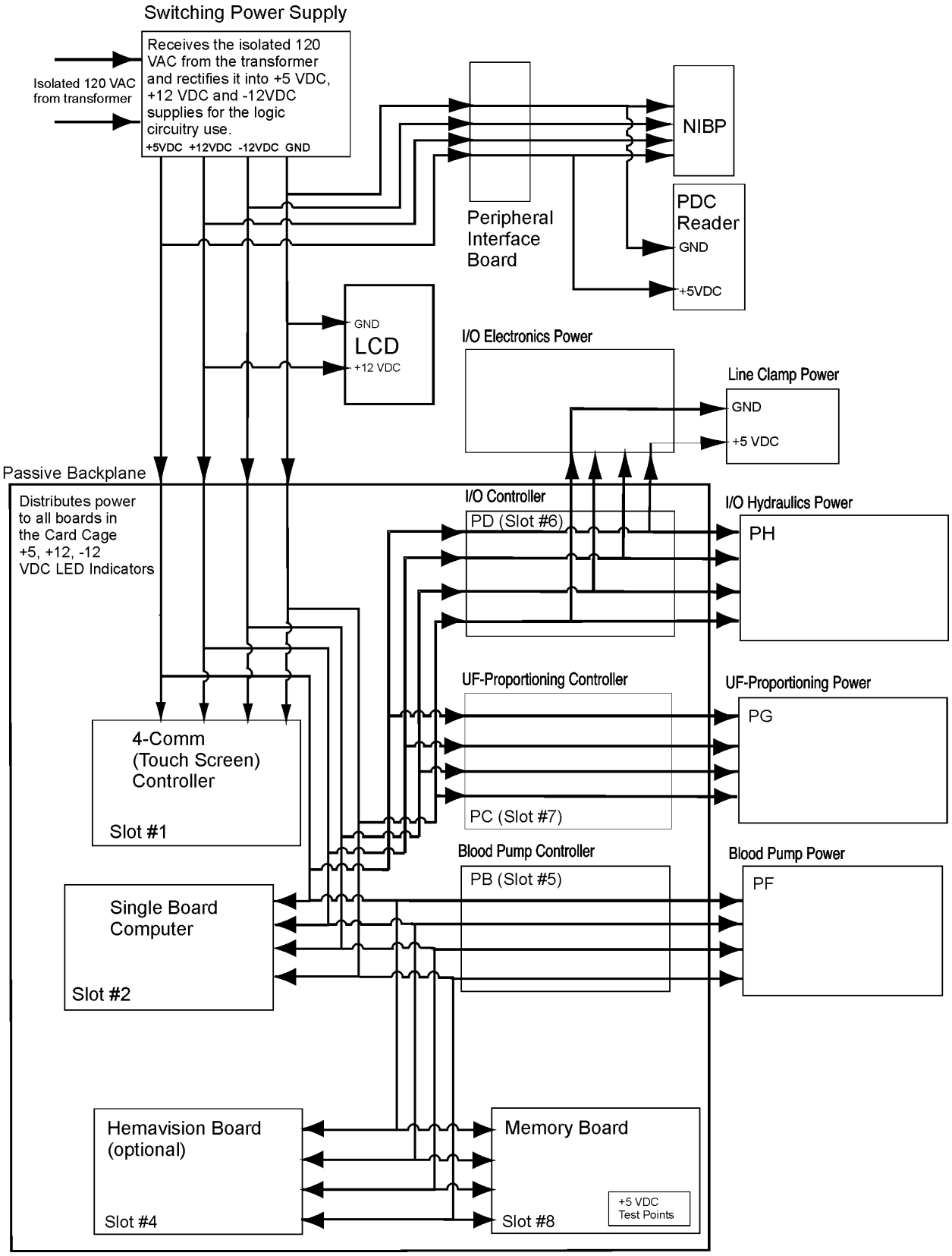

Figure 5-10. Low Voltage Power Distribution

5.4 CARD CAGE

CAUTIONS

1. Use proper ESD protection when handling or contacting any ESD sensitive components.

2. Always repackage the removed ROMs or boards in the original ESD packaging.

The Card Cage houses the electronic boards that will control the operation of the Instrument.

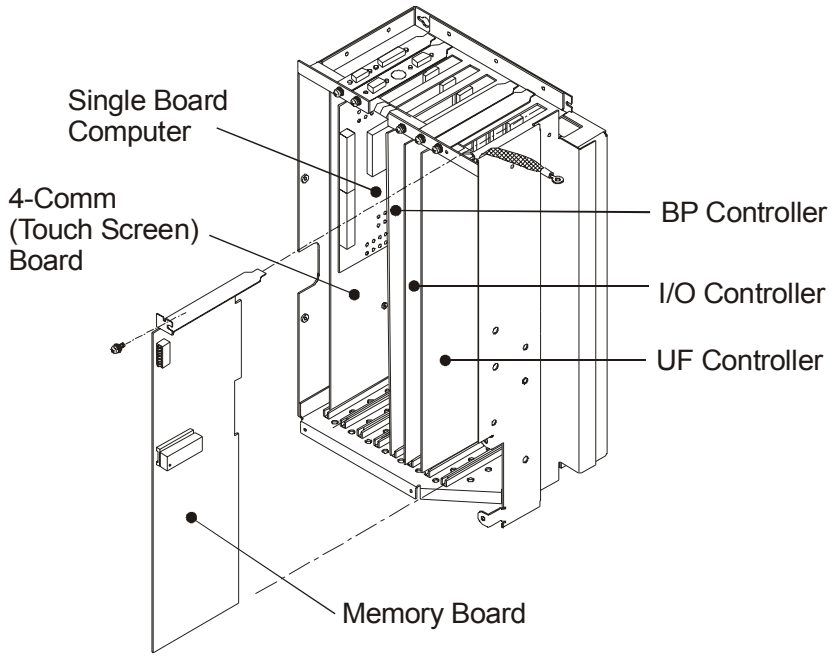

Figure 5-11. Card Cage Standard Configuration

The printed circuit boards that are located here are, from left to right:

- Slot # 1: 4-Comm (Touch Screen) Board
- Slot # 2: Single Board Computer (SBC)
- Slot # 3: None
- Slot # 4: Hemavision Board (optional)

- Slot # 5: Single (or optional Double) Blood Pump Controller
- Slot # 6: Input/Output Controller
- Slot # 7: UF-Proportioning Controller
- Slot # 8: Memory Board

These boards are interconnected through the Backplane located at the back, inside the Card Cage.

5.4.1 Slot # 1: 4-Comm (Touch Screen) Board

This board is the interface between the SBC and the following subsystems:

- Peripheral Interface Board (serial communications with the NIBP and Isolated Serial Port in the Rear Panel)
- Touch Screen
- Optional HDF Board
- Optional Hemavision Board

The Options Key is also located in this board. This key is programmed at the factory with the information related to the options included in your instrument. These options are:

- Powder Bicarbonate (available only in selected markets)
- Citric Acid Heat Disinfection
- Blood Pressure Monitor (enabled by Switch #4 on the Memory Board DIP switch)
- Hemodiafiltration (enabled by Switch #5 on the Memory Board DIP switch)
- On-line Hemodiafiltration
- Single-Pump Single Needle
- Double-Pump Single Needle
- Extended Treatment Time
- Integrated Heat Clean

If this board is replaced, make sure to remove the Options Key from the old board and place it in the new one.

5.4.2 Slot # 2: Single Board Computer (SBC)

The SBC (sometimes also called Motherboard or Host board) is highly integrated, combining video and networking functions in a single board.

5.4.2.1 Hardware

The Instrument is controlled by an Intel Pentium II MMX 266 MHz microprocessor, and three 8040 microcontrollers. The Pentium microprocessor is located in the SBC. The 8040 microcontrollers are located, one each, on the UF-Proportioning Controller board, the I/O Controller board, and the Blood Pump Controller board.

WARNING

Follow proper ESD procedure while handling PCBs.

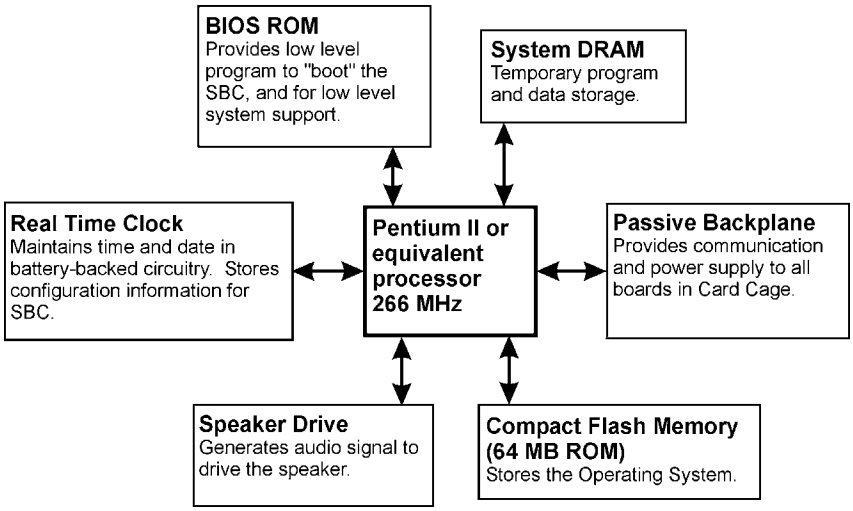

Figure 5-12. SBC Architecture

The Intel Pentium microprocessor supervises the operation of the Instrument, with its primary responsibilities being:

- Flat Panel User Interface (video display and touch screen). Resolution of up to 1024 x 768 @ 64K colors.
- Instrument mode control (Rinse, Prime, Dialyze, etc.)
- Controller communications
- Conducting self tests
- Calibrations

The SBC holds piggy-backed a 64 MB Compact Flash Memory that contains the operating system.

The SBC also has a 64 MB card of System Dynamic RAM (SDRAM). The SDRAM is the memory where the computer

stores programs and data currently being used so they are accessible to the microprocessor. The SDRAM and Compact Flash Memory are not included in the SBC spare, therefore both need to be removed from old SBC and placed on the new SBCs. Follow the next procedure to install the SDRAM on the SBC.

5.4.2.2 SDRAM Installation

1. Observe the orientation of SDRAM module (499-4000-374), SBC (916-5001-494), and position of the notch as shown in Figure 5-13.
2. Insert SDRAM module into connector on Single Board Computer at approximate angle as shown.
3. Push SDRAM module further into the connector keeping the SDRAM module at the same approximate angle until gold fingers at the bottom edge of the SDRAM are completely within the SBC connector.

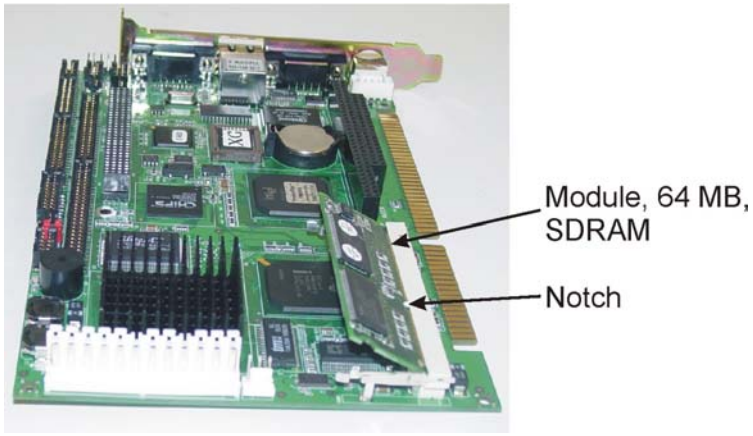

Figure 5-13. Single Board Computer

4. Push down on the top edge of the SDRAM module until it snaps into place as shown in the picture.

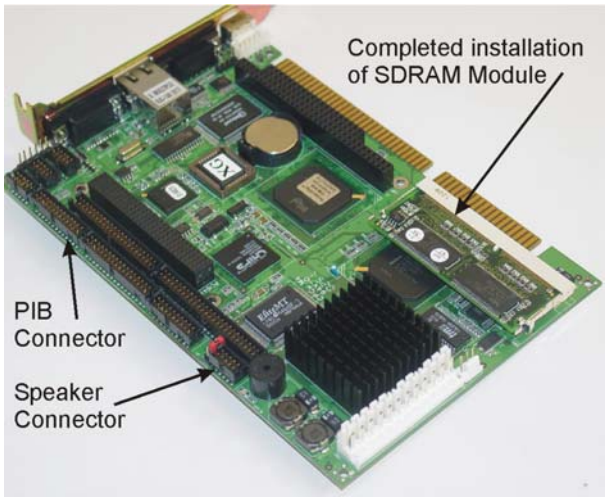

Figure 5-14. Completed Installation

5.4.2.3 BIOS

The Basic Input/Output System (BIOS) program resides in a 256-KB ROM located on the SBC. The BIOS is immediately activated when the Instrument is first hard power on. The BIOS begins the process of checking out the system and configuring it through the Power-On Self Test. When these preliminaries are finished, the BIOS seeks the operating system on the Compact Flash Memory and launches it. The operating system is then run from the SDRAM after loading, providing the framework for executing the host control software. One of the initial activities of the host control software is to read configuration information from the Memory Board's SRAM and the DIP switch positions. The host control software then proceeds into Calibration Mode or Clinical Mode.

5.4.2.4 Hardware Control

The Pentium microprocessor controls the operation of the Instrument through its connection to the following additional boards, which are plugged into the Passive Backplane:

- 4-Comm (Touch Screen) Interface board
- Blood Pump Controller board
- UF/Proportioning Controller board
- I/O Controller board
- Memory Board
- Hemavision (Hematocrit/Blood Volume Monitor) Board (optional)

As mentioned before, 8040 microcontrollers on the three controller boards handle specific Instrument-related functions for the Blood

Pump(s), UF- Concentrate Proportioning, and Input/Output systems. The I/O Controller functions as a watchdog for the Pentium, forcing the system into a nonfunctional safe state if the Pentium discontinues its interprocessor communication.

5.4.2.5 Operating System Software (Host)

The host control software (operating system) is loaded into the 64 MB programmable read only Compact Flash Memory. This memory resides piggy-backed to the SBC.

The purpose of the operating system is to:

- Gather data from the Input/Output, Blood Pump(s) and UF-Proportioning controller sub-systems, and output control functions to the various controller sub-systems.
- Input data from User Interface Touch Screen.
- Monitor the data for violation of alarm limits and unsafe operating conditions, and set the appropriate program alarm condition indicators.
- Update the display data to the video display portion of the user interface.
- Save and retrieve calibration constants in the nonvolatile memory (SRAM on the Memory board), then use the calibration constants during Instrument operation. Refer to Section 5.4.7.
- Monitor the arterial and venous pressures, and generate alarms when they violate their alarm limits. The alarm response includes clamping of the line clamp (via the I/O Controller) and stopping the blood pump (via the Blood Pump Controller).
- Calculate the TMP (transmembrane pressure) by subtracting the dialysate pressure from the venous pressure. Compare the results with the TMP alarm limits, generating an alarm if a violation is detected.
- Serve as a watchdog, ensuring that the Pentium and the three 8040 controllers (one each on the BP, I/O, and UF-Proportioning Controller boards) are functioning.
- Perform the Shutdown Self Test.
- Perform the Pretreatment Self Test.
- Control the active Instrument modes: Calibration, Rinse, Self Test, Prime, Dialyze, Heat Clean, Cool Down or Chemical Disinfection.

- Accept operating information and parameters from the user via the video display touch screen and touch screen controller (for example, blood flow rate, dialysate temperature, UF rate).
- Display operating conditions and status on the video display.

To ensure general integrity of the control system, the following tests are performed during the pretreatment testing.

1. The watchdog function handled by each 8040 microcontroller is tested by individually halting communication to each 8040 and verifying a resulting system shutdown condition.
2. The system's A/D (analog to digital) converters are compared with each other to verify accuracy. Each of the three controller systems (BP, UF, and I/O) utilize A/D converters to provide A/D functions. For Self Test purposes, the A/D outputs from the I/O controller are connected to the A/D inputs of the BP and UF controllers simultaneously. Self testing involves outputting a range of levels through the I/O A/D converter and verifying that similar levels are read by the BP and UF A/D converters.
3. A self-test verification consists of verifying that each self test has successfully executed prior to exiting the Self Test state.

In addition to these pretreatment Self Tests, the following safeguards are in place.

4. An inadvertent transition from the Dialyze state to Rinse is unacceptable because in the Rinse Mode the air detector is disabled and the bypass valve cycles independently of temperature or conductivity alarms, therefore Dialysis during Rinse is prevented by disabling the blood pump when one or both of the dialysate lines are not on their rinse fittings.
5. In addition to this safeguard, before the air detector can be disarmed or the bypass valve can cycle, both the Pentium and the I/O 8040 must be in the Rinse state. Before either enters the Rinse state from Dialyze, the operator must press the RINSE and VERIFY buttons and both dialyzer lines must be verified on their rinse fittings (using the optical interlock switches) and blood can not be sensed at the saline detector.

The SBC filters out the Rinse request from the I/O controller when the dialyzer line interlocks are not in the proper state. The only way the SBC can receive a Rinse request without the proper interlock condition being met is if a failure exists in the system logic. If this situation does occur, then the I/O Controller activates the system shutdown line.

5.4.3 Slot # 4: Hemavision Board (optional)

The Hemavision Board is one of three elements that make up the optional Hemavision Monitor System, and it is located in the Card Cage, Slot # 4, see Figure 5-15. The other two elements are the Hemavision Sensor Clip (see Section 2) that connects directly into this board and the Sensor Clip Test Socket. This system provides a non-invasive method for monitoring the patient's hematocrit, blood volume, and oxygen saturation during the dialysis treatment.

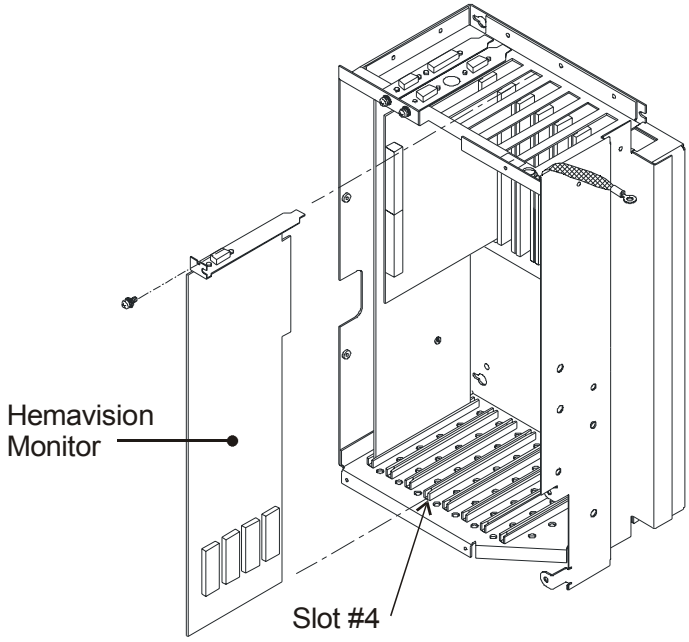

Figure 5-15. Hemavision Board (optional)

Refer to Section 21, Hemavision Monitor, for more information.

5.4.4 Slot # 5: Single (and optional Double) Blood Pump Controller

This board controls the operation of the Blood Pump Power board. For more information, refer to Figure 5-1 and Section 5-5, Blood Pump Power Board.

This board is physically identical to the UF-Proportioning Controller board. There is a different EEPROM for the Double Pump version of the board. The board has a jumper, shown in Figure 5-16, which must be properly placed according to the next Table 5-3, depending on the functions that the board will perform.

Table 5-3. BP/UF Jumper Position

Function	Jumper Position	EEPROM
Single Blood Pump Controller	BP/UF	GC7120S
Double Blood Pump Controller	DP/BP	GC7130S
UF-Proportioning Controller	BP/UF	GC7120S

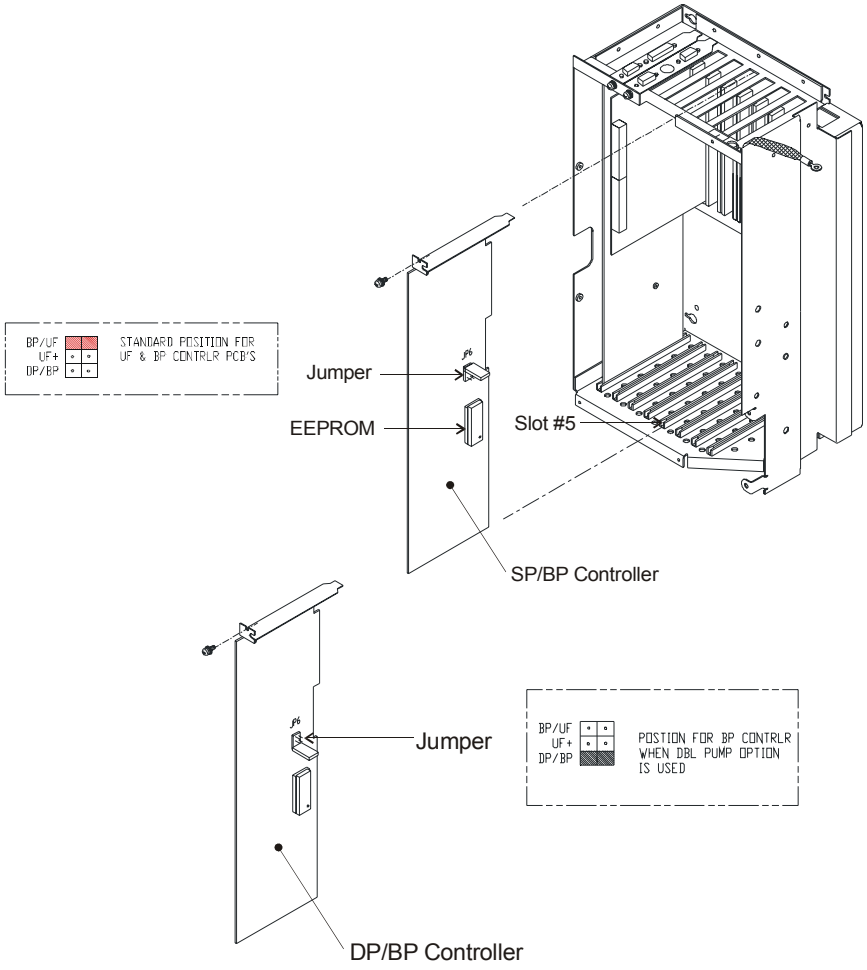

Figure 5-16. Single/Double Pump Controller (a different EEPROM is used on each board)

5.4.5 Slot # 6: Input/Output Controller

This board controls the operation of the I/O Hydraulics Power and I/O Electrical Power Boards, which together form the I/O Control System.

Thirteen subsystems are controlled or monitored by the I/O Control system. They are as follows:

- Air detector
- Blood leak detector
- Dialysate pressure monitor
- Bypass system and flow sensor
- Conductivity monitor
- Temperature monitor
- Line clamp
- Power fail alarm
- Rinse interlocks
- Ambient temperature
- State transition watchdog
- Watchdog timer
- Heparin pump (option) over speed monitor

5.4.6 Slot # 7: Ultrafiltration- Proportioning Controller

This board controls the operation of the UF-Proportioning Power board.

This board is physically identical to the Blood Pump Controller board, however the jumper must be properly positioned according to the function it will perform. Refer to Table 5-3 and Figure 5-16 for further information.

Five subsystems are controlled or monitored by the UF-Proportioning Control system. They are as follows:

- UF System Control
- Concentrates Proportioning Control
- Conductivity-temperature measurement
- Heater Control
- Dialysate Flow Rate Control

5.4.7 Slot # 8: Memory Board

The Memory Board contains the 64 KB non-volatile SRAM (Static Random Access Memory) accessible by software to store the information about calibrations and Instrument parameters. This SRAM has a self-contained battery to keep the data.

This memory contains various parameters for configuration, such as calibration constants and variable data, as well as storage of treatment profiles and patient information. The memory locations are divided into various sections, such that variables can be added without affecting other locations.

Information about various features and implementations of the dialysis machine is also stored in this SRAM.

Calibration Constants

Space is allocated for up to 250 calibration constants accessible from the calibration screen via *Constant Entry* selection. In order to change these constants a password is required.

For compatibility, default values for the calibration constants are contained in the software, and overwrite the SRAM contents if needed.

There are three types of calibration constants:

- Constants that determine the configuration of the machine and are not intended to be changed, such as Display Type, Hydraulics Type, etc.
- Constants that are adjustable during calibration at the time of manufacturing of the Instrument, such as Temperature Probe Gain, BP Motor EMF, etc.
- Constants that allow the Instrument to be customized, such as the Date Format, Bleach Name, etc.

WARNING

Calibration constants must only be changed by authorized Baxter personnel or by specific instructions provided by Baxter.

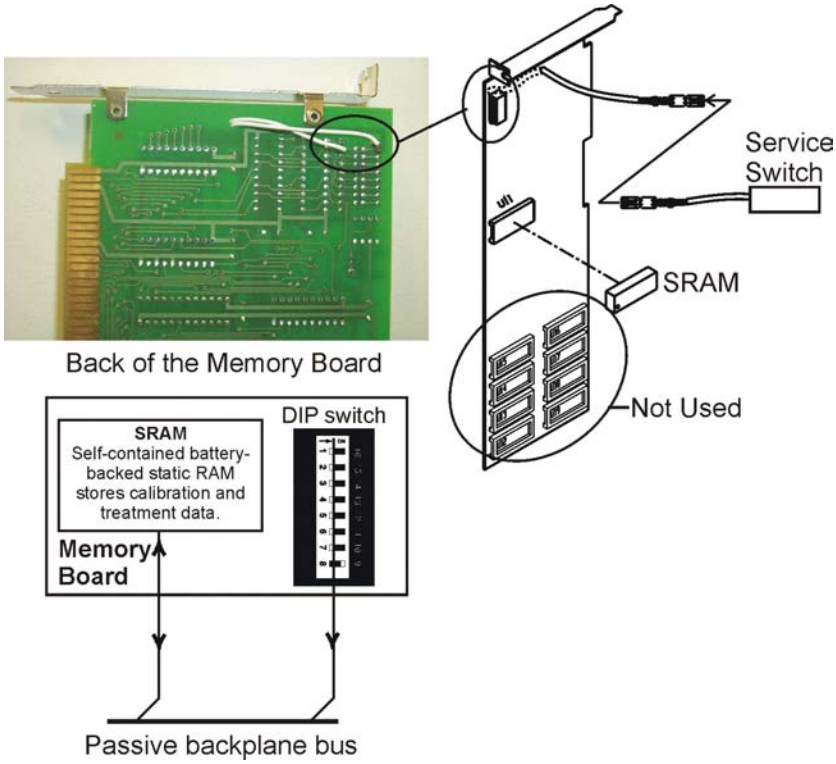

Figure 5-17. Memory Board

The Memory Board provides the following additional functions:

1. System ground and +5 VDC test points
2. Connector for the external Reed Service Switch
3. Address decoding for both memory and I/O devices
4. Treatment Event Log with memory allocated to store the most recent 20 treatment errors, providing date, time and index information
5. Eight-position DIP switch for Instrument configuration control

Table 5-4. DIP Switch Settings

Switch	On	OFF	Default
1	Calibration Mode	Normal operation	OFF
2	Technician Mode	Normal operation	OFF
3	Color Monitor	Must not be used	ON
4	NIBP option is included	NIBP option not included	N/A
5	Hemavision option is included	Hemavision option not included	N/A
6	Not used	Not used	OFF
7	Not used	Not used	OFF
8	Not used	Not used	OFF

Note

When DIP Switch 1 is ON, it allows the Instrument to enter Service/Calibration Mode. The external Reed Service Switch is connected in parallel to this switch and can be used to momentarily turn on Switch 1.

6. UF Profile: space allocated for six profiles, each consisting of up to six hours of treatment data in fifteen minute intervals. Each profile also contains four bytes for setting *UF Only* treatment in fifteen minute intervals
7. Sodium Profile: space allocated for six profiles, each consisting of up to six hours of sodium concentrate level dispensing in fifteen minute intervals
8. Bicarbonate Profile: space allocated for six profiles, each consisting of up to six hours of bicarbonate concentrate level dispensing in fifteen minute intervals
9. Blood Pressure Data
    - Systolic Minimum Limit
    - Diastolic Minimum Limit
    - Systolic Maximum Limit
    - Diastolic Maximum Limit
    - Storage of Associated Time
    - Systolic Pressure
    - Diastolic Pressure
    - Pulse Rate
    - Mean Arterial Pressure
    - Time
    - Type
    - Scheduled / Manual
    - Sitting / Standing
    - Capacity for up to 49 Blood Pressure Records
10. Treatment Setup Recall
    - Storage of previous treatment parameters
    - Prescribed Time
    - Heparin Rate
    - Heparin Auto Shutoff
    - BP Schedule Interval

- Dialysate Flow
- Dialysate Temperature
- Blood Flow
- HCT Limit
- Adjusted NA
- Adjusted BC
- Sodium Profile
- Bicarbonate Profile

5.5 BLOOD PUMP POWER BOARD

This board is controlled directly by the Blood Pump Controller board. It is located right behind and above the blood pumps. The BP Power board in turn controls the operation of the analog devices related to the blood pump system (see Figure 5-1):

- Blood Pumps
- Heparin Pump
- Level Adjust Motors, valves and switches
- Venous and Arterial Membrane switches
- Optional Arterial Line Clamp
- Pressure Transducers
- Speaker power
- Fan
- Sonalert

5.6 UF-PROPORTIONING POWER BOARD

This board is controlled directly by the UF- Proportioning Controller board which incorporates buffering for the gear pumps. The UF- Proportioning Power board in turn controls the operation of some of the analog devices related mostly to the UF-Proportioning system and fluid path (see Figure 5-1):

- Supply Pump
- Dialysate Pressure Pump
- Deaeration Pressure Pump
- End-of-Stroke Sensors
- Heater Control
- UF Flow meter valves
- Flow Equalizer Valves
- A & B Proportioning Pumps
- Dialysate Pressure Relief Valve
- Conductivity-Temperature measurement
- OLHDF Purge Valve # 2 (optional)
- Citric Acid Valve

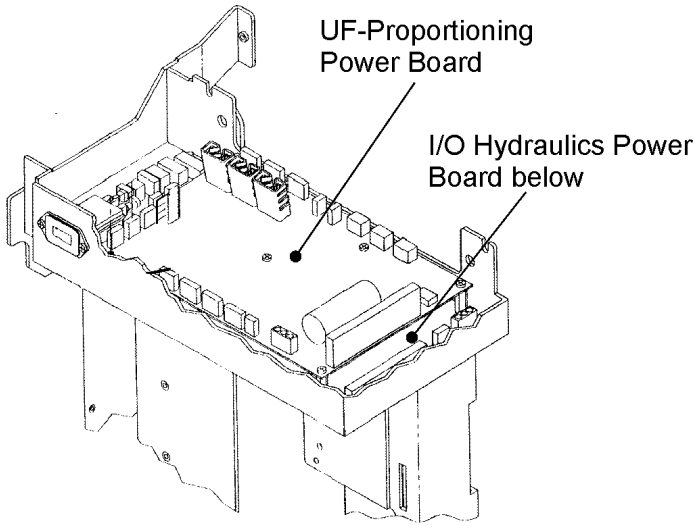

Figure 5-18. UF-Proportioning and I/O Hydraulic Power Board Locations

5.6.1 Fuses

This board incorporates 17 fuses as shown in Table 5-5. Fuses may be removed by grasping them in the center with small pliers.

Table 5-5. UF-Proportioning Power Board Fuses

FUSE	FUSE CIRCUIT	PART NO.	RATING
F1	+24 VDC	6001276132	10 A
F2	+12 VDC	6001276129	0.25 A
F3	+5 VDC	6001276130	0.50 A
F4	-12 VDC	6001276129	0.25 A
F5 - F16	Concentrate pump windings	6001276129	0.25 A
F17	+35 VDC step-up regulator for both concentrate pumps	6001276131	2.0 A

Caution

Do not remove fuse from or insert fuses into the UF-Proportioning Power board while power is applied to the board.

Figure 5-19 shows Fuse F2 removed from the board, while Fuses F3 and F4 are installed. A typical fuse is also shown. Fuses may be continuity tested out of circuit with an ohm meter. Spare fuses may be packaged in a special holder for added protection. Fuses must be removed from that holder before use. See Figure 5-20 for fuses, shown in green.

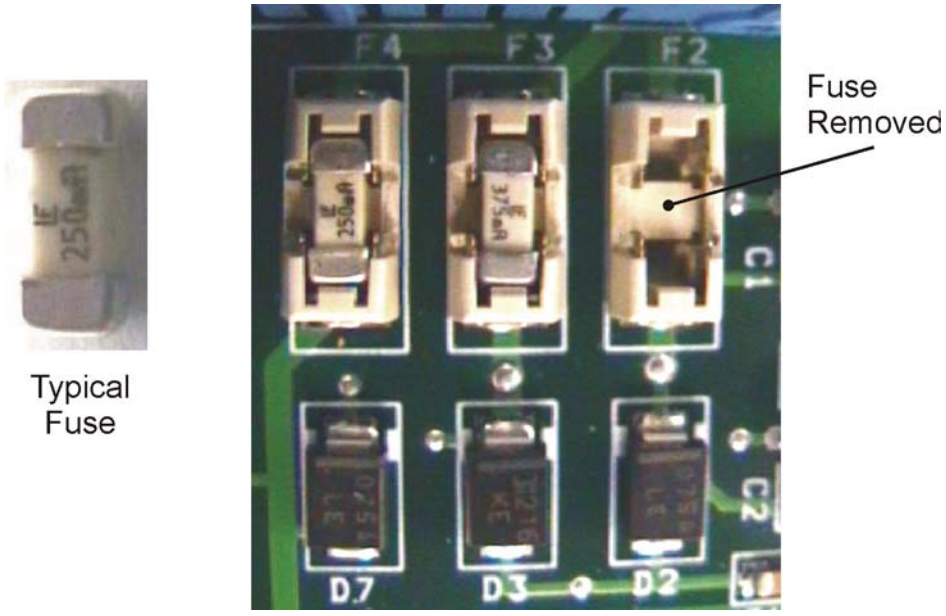

Figure 5-19. UF-Proportioning Power Board Fuses

5.6.2 Light-emitting Diodes (LEDs)

The light-emitting diodes (LEDs) on the UF-Proportioning Power board are located close to the connector for the indicated component drive. See Figure 5-20 for these locations indicated in red.

Table 5-6. UF-Proportioning Power Board LEDs

LED	FUNCTION	COLOR
DS1	+12 VDC	Green
DS2	+5 VDC	Green
DS3	-12 VDC	Green
DS4	Valve 4 Out	Red
DS5	Valve 3 Out	Green
DS6	Heater Enable	Red
DS7	+24 VDC	Green
DS8	+24 VDC Switched	Green
DS9	Flow Equalizer 2 Out	Green
DS10	Flow Equalizer 1 Out	Green
DS11	UF Removal	Red
DS12	Dialysate Pressure Relief Valve	Red
DS13	Valve 2 Out	Green
DS14	"C" Concentrate Pump (not currently used)	Green
DS15	"B" Concentrate Pump	Green
DS16	"A" Concentrate Pump	Green

5.6.3 Test Points

The test points on the UF-Proportioning Power board are listed in the following table. Frequently used test points are marked with an asterisk (*). See Figures 5-20 for test point locations shown in blue.

The +24 V supply can be tested across the large capacitor (C56) near the 60-pin ribbon cable connector.

Table 5-7. UF-Proportioning Power Board Test Points

TEST POINT	FUNCTION TESTED
TP1*	+12 VDC
TP2*	+5 VDC
TP3*	-12 VDC
TP4*	Ground
TP5*	EOS Sensor 1
TP6	Supply Sync
TP7	Supply Control
TP8*	EOS Sensor 2
TP9	Dialysate Pump Control
TP10	Dialysate Pump Sync
TP11	Deaeration Pump Control
TP12	Deaeration Pump Sync
TP13	UF Removal Enable
TP14	DP Relief Enable
TP15	Flow Equalizer 1 Enable
TP16	Flow Equalizer 2 Enable

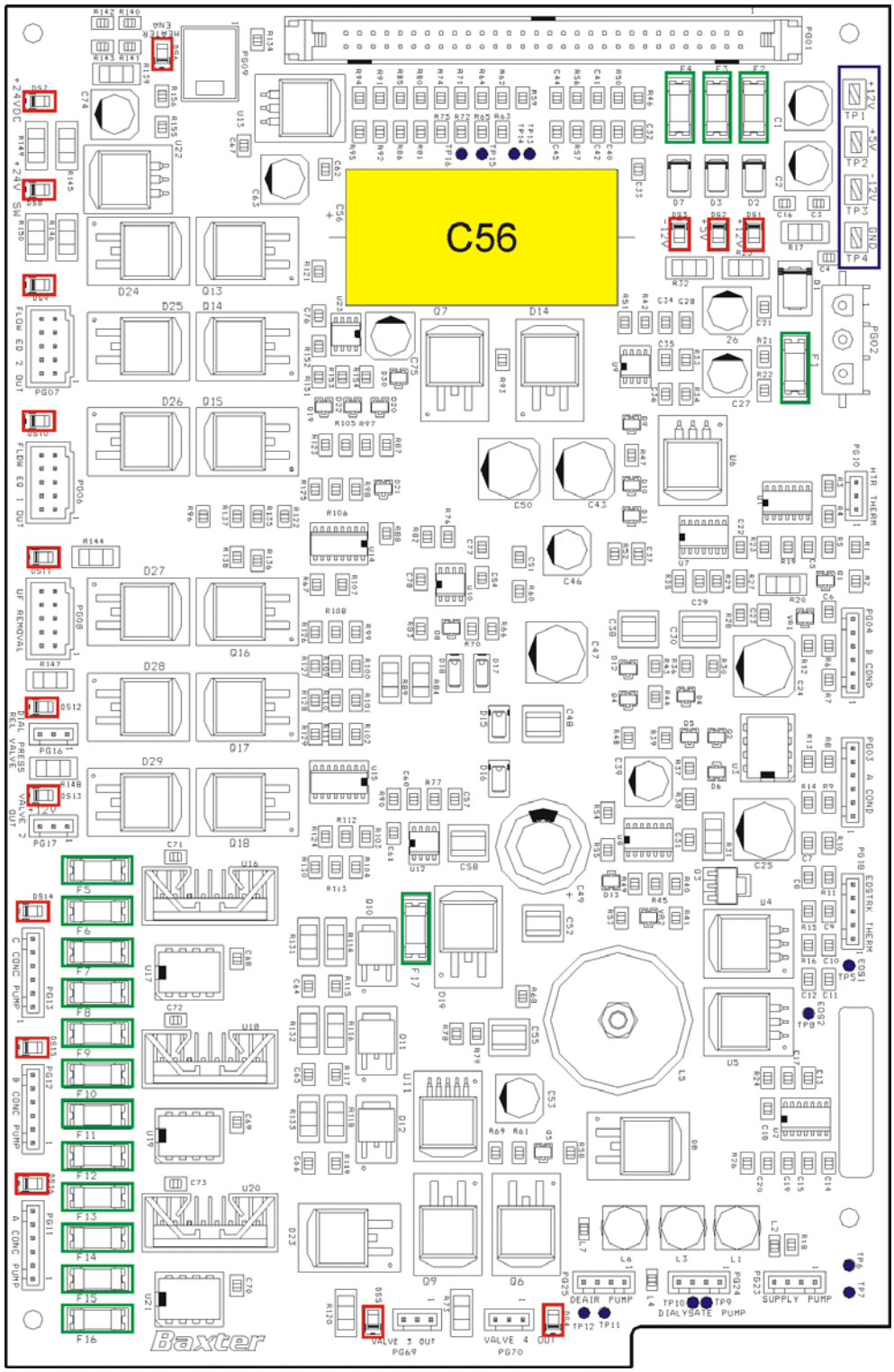

Figure 5-20. UF-Proportioning Power Board with Surface Mount Technology

(Test points are highlighted in blue, LEDs in red, and fuses in green.)

5.7 I/O HYDRAULICS POWER BOARD

This board is controlled directly by the Input/Output Controller board. The I/O Hydraulics Power board in turn controls the operation of the following analog devices related mostly to the fluid path system (see Figures 5-1 and 5-18):

- W/A Level Sensor
- Dialyzer (Rinse) Connector Sensor
- Concentrate Connector Sensor
- Dialysate Flow Sensor
- Hour meter
- Blood Leak Detector
- Dialysate Pressure Transducer
- Conductivity-Temperature monitoring
- Incoming water, Recirculation and Bypass Valves
- OLHDF Purge Valve # 1 (optional)
- Powder Bicarbonate Air Trap Valve and level Sensor, Prime Valves and Cartridge Holder Reed Switch (optional)

Figure 5-21 shows the location of major components, fuses (green), LEDs (red) and test points (blue).

5.7.1 Fuses

Table 5-8 lists fuses with their part numbers and usage. Fuses may be continuity tested out of circuit with an ohm meter. Spare fuses may be packaged in a special holder for added protection. Fuses must be removed from that holder before use.

Fuses may be removed from the board by grasping them in the center with small needle-nose pliers.

Caution

Do not remove fuse from or insert fuses into the Hydraulics Power board while power is applied to the board.

Table 5-8. Hydraulics Power Board Fuses

Fuse	Fuse Circuit	Part No	Rating
F1	+12 VDC Supply	6001276129	0.25 A
F2	+5 VDC Supply	6001276130	0.50 A
F3	-12 VDC Supply	6001276129	0.25 A
F4	+24 VDC Supply	6001276132	10 A
F5	Flow Sensor #1	6001276129	0.25 A

5.7.2 Light-emitting Diodes (LEDs)

Table 5-9. Hydraulics Power Board LEDs

LED	FUNCTION	COLOR
DS1	Flow	Green
DS2	+24 VDC Switched	Green
DS3	+24 VDC	Green
DS4	Heat	Green
DS5	Purge Valve HDF	Green
DS6	Bypass	Green
DS7	+12 VDC	Green
DS8	+5 VDC	Green
DS9	-12 VDC	Green
DS10	P. Prime	Green

5.7.3 Test Points

Table 5-10. Hydraulics Power Board Test Points

TEST POINT	VOLTAGE TESTED
TP1*	+12 VDC
TP2*	+5 VDC
TP3*	Ground
TP4*	+5 VDC
TP5*	Ramp Generator
TP6	Conductivity Ref
TP7	Flow Sensor #1 (Flow Ref)
TP8*	Flow Sensor #2 (Temp Ref)
TP9	Flow Control
TP10	Heat Recirculation Valve Control
TP11	Powder Valve Control
TP12	Bypass Valve
TP13	On/Off Valve
TP14	Interlock Drive
TP15	P. Prime Control

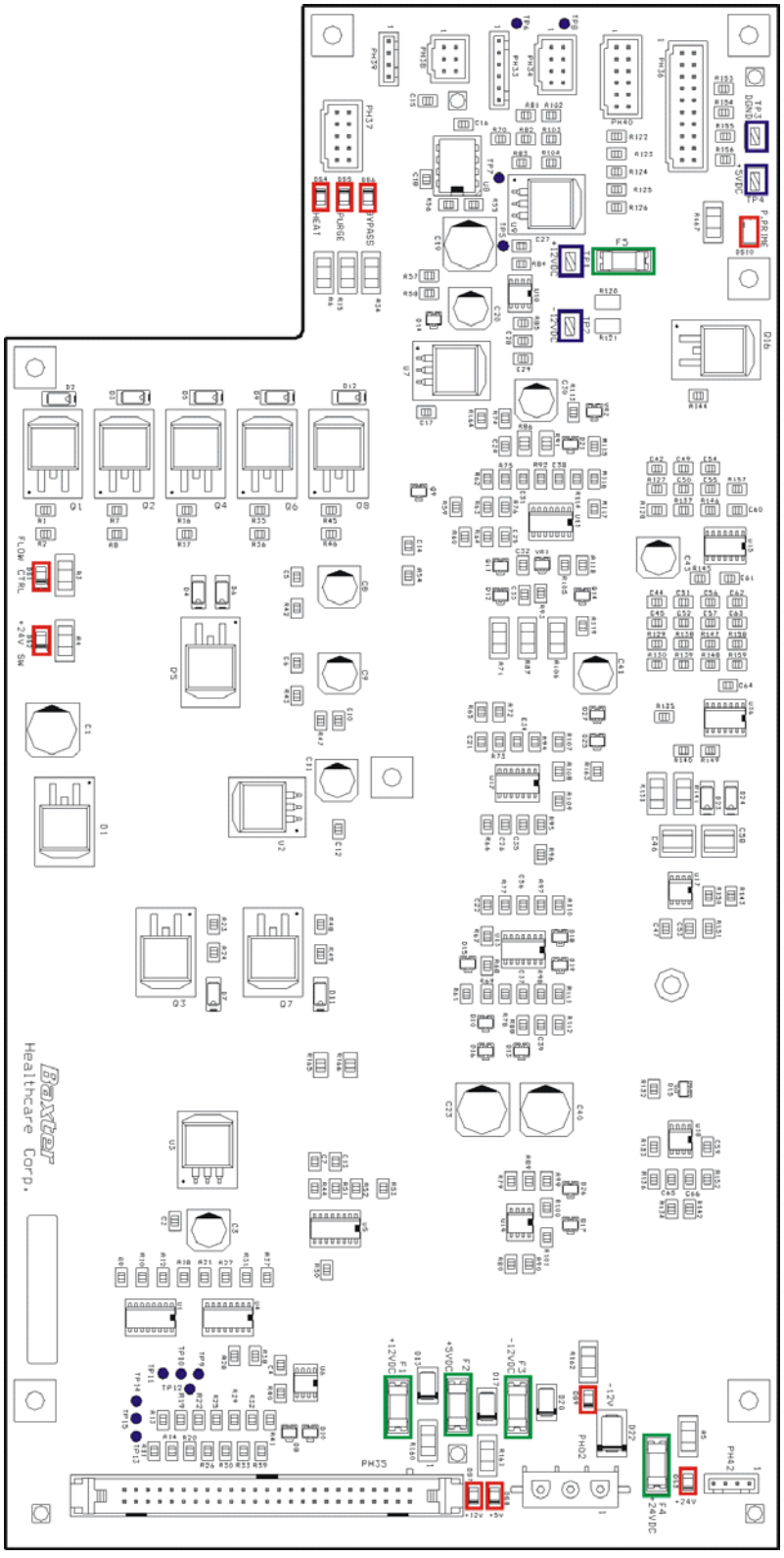

Figure 5-21. I/O Hydraulics Power Board with Surface Mount Technology

(Test points are highlighted in blue, LEDs in red, and fuses in green.)

5.7.4 Bypass System and Flow Sensor

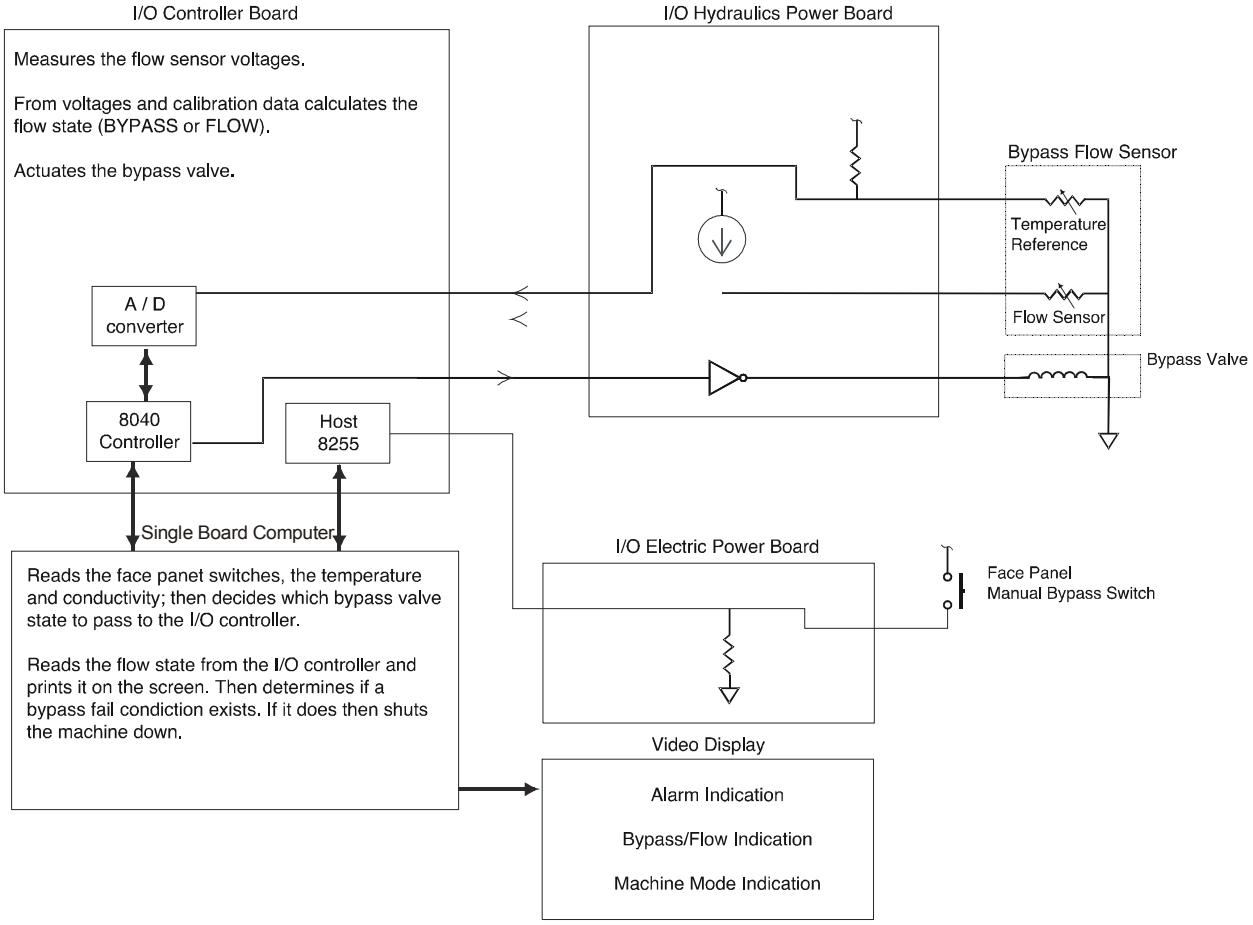

Figure 5-22. Bypass System

The Bypass Mode is initiated when a primary dialysate alarm is detected by the I/O Controller board, when a redundant dialysate alarm is detected by the UF-Proportioning Controller board, when the host requests bypass, or when the manual bypass button is pushed.

The bypass valve is in the bypass position when de-energized. It is driven from the nominal +24 VDC supply with an on/off transistor control on the I/O Hydraulics Power board.

To verify that there is not a failure in the bypass system, a flow sensor just downstream of the predialyzer bypass valve checks for flow. If flow exists during the bypass mode, a Bypass Fail Alarm is set and the Instrument is put in the safe, nonfunctional, Shutdown state. If there is no flow when not in the bypass mode, a No (dialysate) Flow alarm is generated.

This flow sensor consists of two thermistors. The first is a reference thermistor used to determine the fluid temperature. The

second thermistor uses thermal dilution to sense the fluid flow. The voltage outputs from the thermistors on the I/O Hydraulics Power board drive A/D input channels on the I/O Controller board where they are converted to 10 bit digital values. A software algorithm in the I/O Controller code uses these inputs to determine the flow condition. The design of the voltage divider guarantees that the output remains within the A/D input range of 0 to +5 VDC over the input temperature/flow range and over all component tolerances.

5.8 I/O ELECTRONICS POWER BOARD

This board is also controlled directly by the Input/Output Controller board. The I/O Electronics Power board in turn controls the operation of some of the analog devices related mostly to the extracorporeal circuit (see Figure 5-1):

- Air & Saline/Blood Detector
- Venous Line Clamp Driver
- Membrane Panel Switches
- Sonalert Control
- Power Fail Alarm. The power fail alarm circuitry is located on the I/O Electronics Power board. See next drawing:

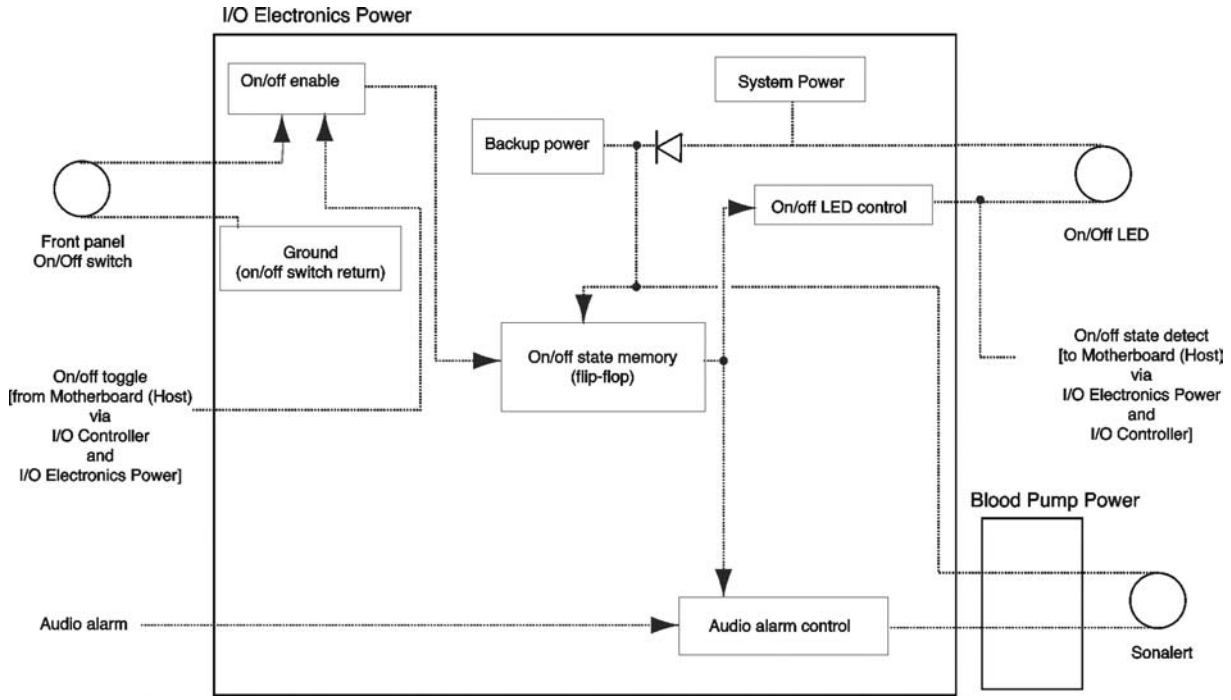

Figure 5-23. On/Off State, Audio Alarm, and Power Fail

The power fail alarm circuitry includes a CMOS power state flip-flop powered by a 1 Farad (F) capacitor. The flip-flop, which can be toggled by either the front panel power button or the Pentium system controller, provides the following functions:

- When power is not supplied to the Instrument (the +5 V supply is off) and when the flip-flop is in the on state, then power is supplied from the 1 F capacitor to the audio alarm device. When power is supplied to the Instrument, the flip-flop's output state is read by the Pentium, which provides indication of the intended Instrument power state. Also, when the flip-flop is in the on state, power is supplied to the front panel power switch LED.
- The power fail alarm occurs either if the Instrument loses power while it is running, or if the front panel power button is pressed "on" when there is no power supplied to the Instrument. The alarm can be silenced by toggling the flip-flop off by pressing the front panel power button.

5.9 PERIPHERAL INTERFACE BOARDS

The Peripheral Interface Boards consist of the Peripheral Interface Board and the Rear Passive Interconnect Panel (two passive boards containing only connectors). The Peripheral Interface Boards provide a physical link, communications, and power between some of the SBC ports and the peripheral devices.

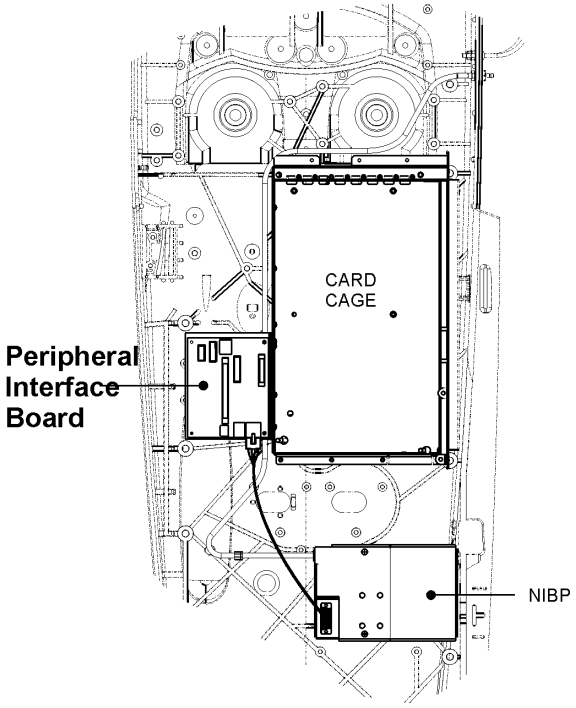

Figure 5-24. Peripheral Interface Board

The Rear Passive Interconnect Panel provides physical connection for the external peripherals linked to the SBC's parallel port.

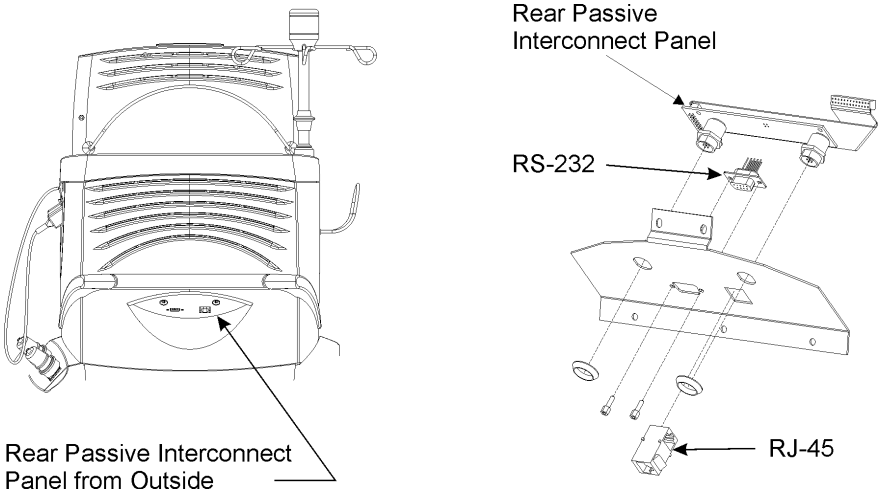

Figure 5-25. Rear Passive Interconnect Panel (Outside Rear and Exploded Views)

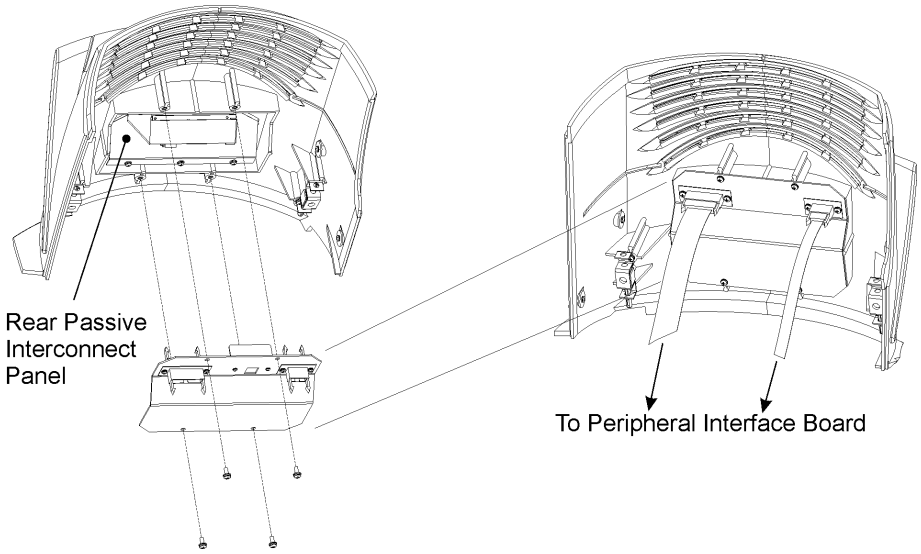

Figure 5-26. Rear Passive Interconnect Panel (Interior Views)

The interface boards provide the necessary circuitry required to create a link between the parallel port of the SBC and the following peripherals:

- Patient Data Card Reader
- Sodium Button pendant
- 3-Light status lamp

In addition to the parallel port interface, the interface boards also provide an isolated RS-232 serial port to an external device and a serial channel and power to the internal Non-Invasive Blood Pressure Monitor (NIBP) subsystem.

Note

Interface of the SBC's Ethernet to the rear panel outlet is achieved through cabling. The Instrument interface boards are not involved with this function. This feature is not yet available.

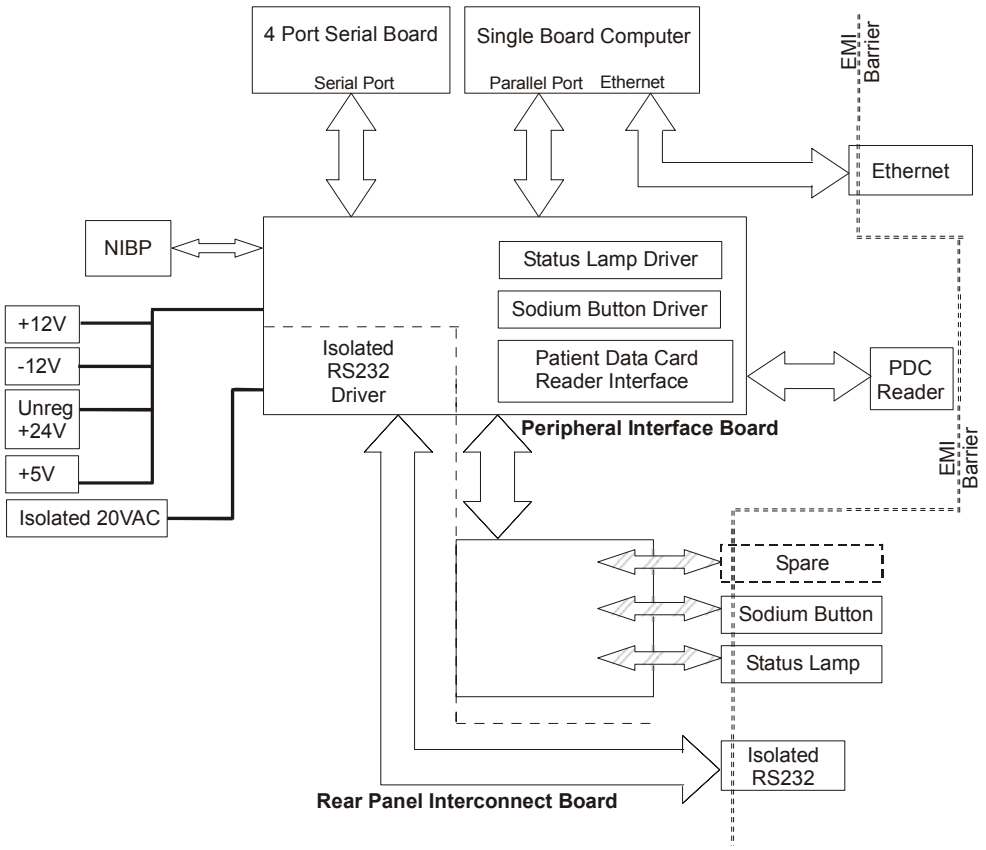

Figure 5-27. Peripheral Interface Boards Block Diagram

The Rear Passive Interconnect Panel provides physical connection for the peripheral devices:

- 3-Light Status Lamp
- Sodium Button Pendant

Two additional connectors are located on the Rear Passive Interconnect Panel:

- Isolated serial port RS-232
- Ethernet port RJ-45

Additional peripheral devices not linked to the Rear Passive Interconnect Panel are:

- Patient Data Card Reader
- Non-Invasive Blood Pressure Monitor

The Peripheral Interface Board can be analyzed from two different points of view: Functional and Electrical.

5.9.1 Functional

- **Power.** This section provides power to the Peripheral Interface Board and its peripherals.
- **Parallel Port.** The Peripheral Interface Board is directly connected to the SBC's parallel port. The parallel port controlled section comprises three functions: Status Lamp, Sodium Button, Patient Data Card Reader. The status lamp and Sodium Button peripherals are physically connected to the Rear Passive Interconnect Panel while the Patient Data Card Reader is physically connected to the Peripheral Interface Board.
- **Serial Ports.** The Peripheral Interface Board is directly connected to the touch screen board (4-Comm Board), which is controlled by the SBC. The serial ports section comprises two functions: serial port communications to the Non-Invasive Blood Pressure Monitor and isolated serial port communications to an external device.

5.9.2 Electrical

- **System.** Includes the parallel port controlled section, one of the Serial Ports, one half of the second serial port, the unregulated +24 VDC (+29.5 VDC +/- 3V DC), +12V DC, -12 VDC, and the +5 VDC power supplies of the power section.
- **Isolated.** Includes the remaining part of the second serial port, the 20 VAC and the isolated +5 VDC.

The rear panel passive interconnect board provides interface through the rear panel to the status lamp and Sodium Button of the system section.

The rear panel (metal plate) holds the rear panel interconnect board, the isolated serial port connector and the ethernet connector.

The interconnect diagram in Figure 5-1 includes the Peripheral Interface Boards. Table 5-11 lists the LEDs and fuses associated with the Peripheral Interface Boards. The fuses used in this board are surface mounted, as shown in Figure 5-19. Additional fuses are listed in Section 5.10.

Table 5-11. Peripheral Interface Board LEDs and Fuses

LEDS/FUSES	SYSTEM	PART NO.
DS1	Patient Data Card Power (software controlled)	NA
DS2	Sodium Button Pendant Switch pressed (hardwired)	NA
DS3	Patient Data Card Inserted (hardwired)	NA
Fuse 1	+24 VDC to the 3-Light Status Lamp Rated @ 0.25 A, 125 VAC	4560388015
Fuse 2	+5 VDC into the Peripheral Interface Board (RS-232 and Sodium Button) Rated @ 0.25 A, 125 VAC	4560388015
Fuse 3	20 VAC from transformer. Serial communication to the back panel Rated @ 0.125 A, 125 VAC	6001278528

5.10 FUSES

Fuses for the UF-Proportioning Power board, Hydraulics Power board and Peripheral Interface boards are found in Tables 5-5, 5-8 and 5-11.

Table 5-12 is a listing of all additional fuses and circuit breakers used on the Instrument.

Table 5-12. Fuse Listing

QTY	RATING*	SIZE**	REF	LOCATION	P/N	COMMENTS
1	T 20 A 240 VAC	Circuit Breaker	CB1	Base, Lower Rear	G119200	110/120 VAC configuration
1	T 10 A 240 VAC	Circuit Breaker	CB1	Base, Lower Rear	G106800	Transformer 230/240 VAC configuration
1	T 6.0 A 250 VAC	Circuit Breaker	CB2	Base	G121300	Transformer 110/120 VAC configuration
1	T 3.5 A 250 VAC	Circuit Breaker	CB2	Base	G121400	Transformer 230/240 VAC configuration
1	T 2.0 A 250 VAC	5 x 20 mm	F1	Terminal Block	G142300	Isolated 120 VAC for Switching Power Supply & Venous Line Clamp
1	T 3.0 A 250 VAC	SMF	FS1	SBC	N/A	Mouse and keyboard
1	T 3.0 A 250 VAC	5 x 20 mm	F1	Switching Power Supply	N/A	Included in the power supply
1	F 10 A 250 VAC		F1	Unregulated +24 VDC Power Supply	E02160000	N/A

Table Notes:

* *F = Fast-acting*
T = Time-delayed (SLO-BLO™)
VF = Very fast-acting
** *SMF = Surface Mount Fuse*

ARENA INTERCONNECT DIAGRAM

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Arena Interconnect Diagram

157-1278-586 Rev A 11-03-03

Upper Chassis

Patient Data Card Reader

Peripheral Interface Board
J1, J7, J6, J9, J8, J2, J3, J5

Alarm Lamp

Level Adjust Motor And Valves

Speaker

+12 VDC
15-Inch Color LCD display

Touch Screen

Membrane Panel Switches

Optional Regulator +20 VDC

PF
Sonalert
Blood Pump Power Bd.
PF22, NA, Cabinet Temp. Sensor, ART Transducer JF28, VEN Transducer JF29, SND Transducer JF30
PF26, PF25, PF21, PF32, PF20, PF31, PF50, PF23
PF02, PF27, PF24
P3, P2

Hema Clip

Venous, Arterial

Secondary Blood Pump (Optional)

Primary Blood Pump

Heparin Pump

DB9

Card Cage

P1, P2 — 4-Comm (Touch-Screen) Bd. — Slot #1

CN5, CN13 — Single Board Computer (SDRAM, Flash Compact Memory) — CN9, CN1, JP3, P2 — Slot #2

Empty — Slot #3

J2 — Hemavision Bd. (optional) — J9 — Slot #4

PB25, PB — Blood Pump Controller Bd. — Slot #5

PB52, PD52 — Input/Output Controller Bd. — Slot #6 — PD43, PD35

PD52, PC52, PC01, PC — UF-Proportioning Controller Bd. — Slot #7

J1 — Memory Bd. (Non-volatile SRAM, DIP Switch) — Slot #8

Passive Backplane
+5,+12, & -12 VDC LED Indicators
Speaker
PW1 Filter

Service Reed Switch

Speaker

Alarm Lamp

Peripheral Devices Rear Connection Panel

Sodium Button (Optional)

Passive Rear Panel Int. Bd.

3-Light Status Lamp

Serial Comm. — RS 232

Ethernet — RJ45

Lower Chassis

Venous Line Clamp Driver Board
PK, PK51, PK49

Venous Line Clamp

Arterial Rotary Line Clamp (optional)

Blood Pressure Monitor (optional)

PI, PI49, PI50, PI43, PI45
Input/Output Electronics Power Board
Cabinet Temperature Sensor
PI63, PI44, PI02

Sonalert

Blood/ Saline Detector

Air Detector

TB2
Switching Power Supply
TB1
+5 VDC Alarm Lamp Power

Hydraulics Module

A Conc. Pump

B Conc. Pump

Dialysate Pressure Relief Valve

EOS Sensors — 2, 1

Supply Pump

Dialysate Pump

Deair. Pump

A Cond. Probe

B Cond. Probe

PG
PG09, PG11, PG12, PG16, PG18, PG23, PG24, PG25, PG03, PG04
UF/ Proportioning Power Board
PG10, PG01, PG08, PG69, PG70, PG07, PG06, PG02, PG05

UF Removal Meter
Valve 1
Valve 4
Valve 2
Valve 3

Citric Acid Valve (Optional)

OLHDF Purge Valve #2 (Optional)

Valve 8, Valve 5, Valve 3, Valve 2
Valve 7, Valve 6, Valve 4, Valve 1
Flow Equalizer Assembly

C Cond. Probe (Not Used)

PH
PH35
Input/Output Hydraulics Power Board
PH02
PH33, PH34, PH34, PH34, PH36, PH36, PH36, PH37, PH37, PH38, PH39, PH40, PH40, PH42

Primary Conductivity Probe

Dialysate Flow Sensor

Powder Cartridge Holder Reed Switch (optional)

Powder Air Trap Level Sensor (optional)

Concentrate Interlock

Powder Air Trap Valve

Powder Prime Valves (Optional)

Dialysate Pressure Transducer

Main Level Sensor

Rinse Block Interlock

Hour Meter

Blood Leak Detector

Thermistor

Solid State Relay

Safety Thermostat

Heater

OLHDF Purge Valve #1 (Optional)

Flow Control Valve
Recirculation Valve
Bypass Valve

Base

Fan

HDF Scale (optional)

P3, P4
HDF Power Supply Board (optional)
P1 & P2

PM66
Unregulated Power Supply
JM19
PM02

Isolation Transformer

CB2

Terminal Block

F1

Mains Circuit Breaker
20 A or 10 A
CB1

Power Cord

RFI Filter

Red Solid Line- Power
Blue Dotted Line-Communication
Green blocks- Printed Circuit Boards
Ribbon Cable
Connector

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Arena

6. TEMPERATURE CONTROL

6.1 OVERVIEW

The **Arena** Instrument accurately and safely controls the temperature of the dialysate using a redundant system. This redundancy involves two electronic signals that pass through separate electronic pathways (the UF-Proportioning and the I/O Controllers) which encompasses two main objectives:

- Control the dialysate temperature to the temperature selected by the operator and back up temperature alarm (see Section 6.2)
- Dialysate temperature monitoring and primary temperature alarm in case there is any failure in the control system (see Section 6.3)

This redundant system uses a total of three separate temperature probes in the Instrument delivery system: the heater control thermistor, and the "B" and Primary conductivity probes.

The "A" temperature sensor, also located in the "A" conductivity probe, is not used to control the temperature of the dialysate. It is only used to compensate the conductivity reading due to variations in temperature.

Another function of the temperature control system is to control the cabinet (internal) temperature at a level at which the electronic components are guaranteed to operate properly. This is accomplished using circuits unrelated to the dialysate temperature control. The sensors for the cabinet temperature are located on the Blood Pump Power Board and the I/O Electronics Board (see Section 6.5).

6.2 TEMPERATURE CONTROL AND BACK UP TEMPERATURE ALARM

This system is managed by the UF-Proportioning boards. The UF–Proportioning system measures the dialysate temperature at three locations in the fluid path. The first location is directly after the heater, and this thermistor (the heater control thermistor) is used for the main temperature control feedback. The heater thermistor, located on the output of the heater housing, signal is biased on the UF-Proportioning Power board. (There is also a safety thermostat located within the heater housing.) This signal is passed to the

A/D converter on the UF-Proportioning Controller board. The signal has calibration factors applied and the result is compared to the user-requested temperature.

The second and third thermistors are contained in the “A” and “B” conductivity probes. The "B" thermistor is used to generate a redundant backup high alarm and provides fine control of the temperature. The Primary thermistor provides the primary temperature alarm. These thermistors are also used to temperature-compensate the conductivity measurements.

The following detailed steps occur during the dialysate temperature control. Refer to Figure 6-1.

1. The operator enters the desired dialysate temperature through the touch screen, and this information is sent to Single Board Computer (SBC) via the 4-Comm (Touch Screen) board.
2. The SBC converts the desired dialysate temperature into the “B” thermistor temperature calibration, using the appropriate calibration constant stored in the SRAM in the Memory board, and sends it to the UF–Proportioning Controller board.

   Calibration of the temperature measurements is a two-point calibration done at 32 and 40°C. The calibration procedure results in a calibration constant for both the slope and the offset for each temperature probe/circuit.
3. The UF-Proportioning Power Board reads the temperature from the heater control and “B” temperature probes on a scheduled basis (every 0.2 second for the “A” and “B” temperatures and every 1 second for the heater control temperature).
4. The UF-Proportioning Controller board reads and converts into a digital signal the heater control and “B” temperature probes signals from the UF-Prop Power board, and sends this information to the SBC.
5. The SBC reads the “B” probe temperature from the UF-Proportioning Controller. When the temperature is determined to be stable, the host offsets the control temperature by the difference between the “B” probe temperature and the user-set control temperature.

   The host-determined temperature correction is calculated using the temperature entered by the user and the stable “B” conductivity probe temperature. If the stable “B” conductivity probe temperature is different from the user-

set temperature by more than 0.05°C, then the control temperature threshold sent to the UF–Proportioning controller is updated, changing the temperature control so that the "B" conductivity probe temperature will equal the user-set temperature. Using this correction routine, the dialysate temperature at the "B" conductivity probe is adjusted so that flow rate, ambient temperature, concentrate type, and temperature effects on the "B" conductivity probe temperature (and the primary temperature, displayed on the video screen) will be compensated. This control temperature adjustment is performed a maximum of every 5 minutes.

6. The UF-Proportioning Controller board, using the information (step 2) from the SBC and the heater control temperature probe, controls the heater duty cycle through the UF Power board to increase or decrease the temperature as required by enabling a solid state relay which provides the power to the heater with a 5 Hz pulse-width modulated digital signal (heater enable signal).
7. The UF-Proportioning Controller generates a backup high temperature alarm when the "B" probe temperature is higher than the host-initialized high temperature alarm limit (maximum limit of 41ºC), and no primary dialysate temperature alarm exists.
8. The UF-Proportioning Controller directly deactivates the bypass valve (removing flow to the dialyzer) during a backup temperature alarm.
9. The SBC reads the the measured temperature (from the I/O Controller), the set temperature, and alarm indication from the UF-Proportioning Controller, and displays them on the LCD. BACKUP is displayed above the temperature window if the"B" probe back up high temperature alarm is triggered.
10. There is a resettable safety thermostat in the heater assembly that will remove power to the heater at 107ºC (225 ºF).

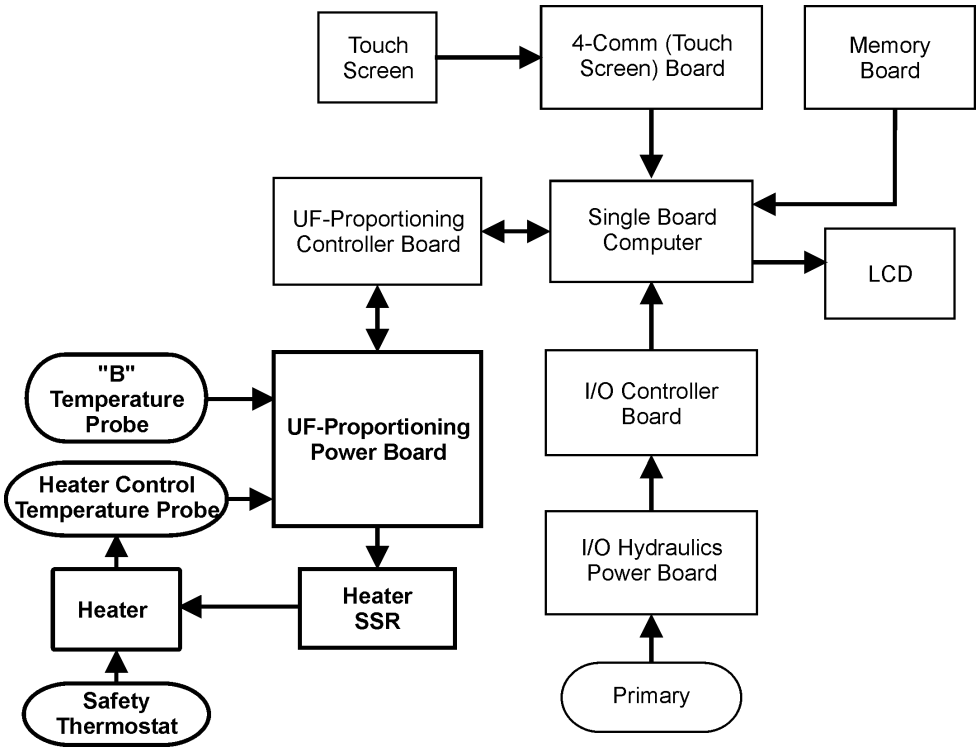

Figure 6-1. Temperature Control Block Diagram

6.3 TEMPERATURE MONITORING AND PRIMARY TEMPERATURE ALARM

This system is managed by the I/O and Hydraulics boards. The temperature monitoring follows steps similar to temperature control:

1. The operator enters the desired dialysate temperature through the Touch Screen, and this information is sent to Single Board Computer (SBC) via the 4-Comm (Touch Screen) board.
2. The SBC converts the desired dialysate temperature using the appropriate calibration constant stored in the SRAM in the Memory board, and sends it to the I/O Controller board. The calibration gain has a ±12% adjustment range around the nominal and the calibration offset has a ±5°C adjustment range. The gains and offsets for the thermistors are also stored in the memory board, in the nonvolatile SRAM for later retrieval and use during the Instrument initialization.
3. A thermistor at the Primary Conductivity Probe provides the signal for the I/O Controller via I/O Hydraulics Power

board for comparison against the primary temperature alarm limits as well as temperature compensation for the primary conductivity.

4. The I/O Hydraulics Power board reads the temperature from the primary temperature probe.
5. The I/O Controller board reads and converts into a digital signal the primary (dialysate) temperature probe signal from the I/O Hydraulics Power board, and sends this information to the SBC.

   The Primary temperature probe is located in the dialysate manifold.
6. The I/O Controller board provides technician-adjustable high and low alarm limits indirectly (via the SBC) triggering audible and visual alarms.
7. The I/O Controller generates a high or low temperature alarm (user-selectable maximum between 39 and 41°C, and minimum between 34 and 36°C) when the primary temperature passes either threshold.
8. The SBC reads the the primary (measured) temperature from the I/O Controller, and alarm indication from the I/O Controller, and displays them in the LCD. ALARM is displayed by the SBC in the LCD, above the temperature window.
9. Under the command of the I/O Controller board, the I/O Hydraulics Power board directly deactivates the bypass valve during a primary temperature alarm, therefore removing flow to the dialyzer.

6.4 AUTOMATIC SAFETY TESTS

Since the UF-Proportioning microcontroller is responsible for controlling the temperature, the I/O microcontroller provides an independent safety system. The safety system contains three major components whose functions are verified during self test at the beginning of each treatment. These are:

- The I/O Controller's ability to measure the dialysate temperature using the primary conductivity probe thermistor
- The I/O Controller's ability to alarm off of a temperature outside of the SBC supplied alarm limits
- The I/O Controller's ability to deactivate the bypass valve

The following tests are therefore performed during Self Test to guarantee a fully functional system.

1. **Primary probe temperature measurement accuracy test**

   The SBC compares the I/O Controller's primary probe measurement with the UF-Proportioning Controller's measurement of the “B” probe’s temperature reading and verifies that they are within 1°C of each other. In addition, the primary dialysate temperature is continuously displayed on the front panel, allowing user verification of its accuracy.

2. **I/O temperature alarm test**

   The SBC consecutively generates both primary temperature alarms by first setting the upper alarm limit to a value below the current temperature, and then by setting the lower alarm limit to a value above the current temperature. An upper alarm is also generated through hardware by shunting the primary probe thermistor with a resistance. In each case, a reported alarm condition from the I/O Controller board is verified by the SBC.

3. **UF/Prop temperature alarm test**

   The backup high temperature alarm in the UF-Proportioning Controller is tested by moving the alarm limit so that it forces an alarm condition. The alarm response is then verified.

6.5 INTERNAL CABINET TEMPERATURE CONTROL

The purpose of the cabinet cooling system is to keep the internal temperature of the cabinet lower than 50°C. Most electronic components are rated to operate at 60°C (local ambient). An internal fan, with an externally accessible dust filter, located at the base of the Instrument (see Section 2) draws in ambient room temperature air to cool the electronics of the Instrument.

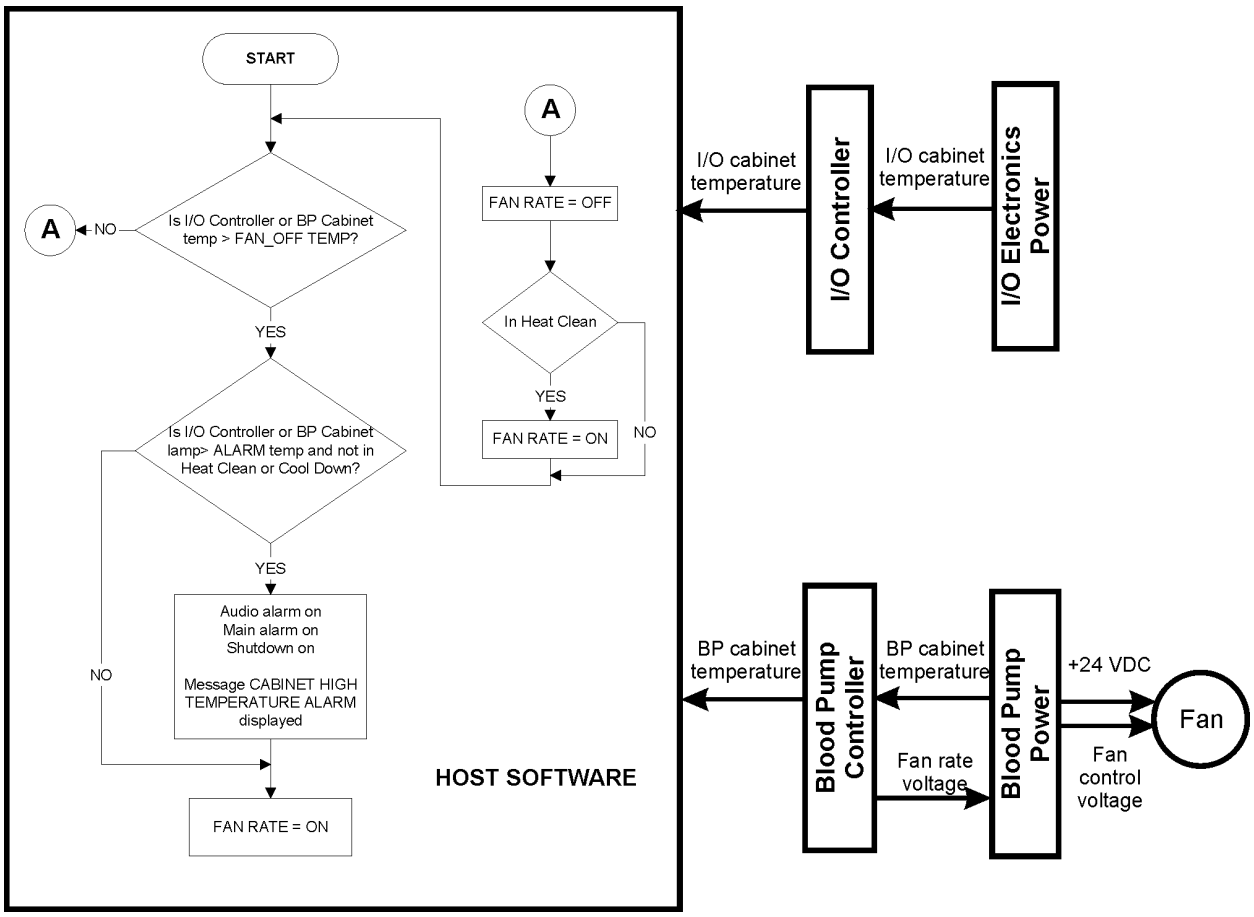

Figure 6-2. Cabinet Temperature Control

The air rises, and positive pressure and thermal convection combine to exhaust the warmed cabinet air out the top of the instrument through exhaust vents on the upper back and upper display back of the Instrument.

The cabinet cooling system consists of the following major components:

Table 6-1. Cabinet Temperature Control Components

Description	Location
Cabinet Fan	Base of Instrument
Blood Pump Temperature IC	Blood Pump Power Board
I/O Temperature IC	I/O Electronics Power Board
Software Fan Control	Single Board Computer
Cabinet Fan Drive	Blood Pump Power Board

As shown in the previous table, the temperature integrated circuits (ICs) are located on the Blood Pump and I/O Electronics Power boards. The ICs output a voltage linear with the temperature in the

cabinet (10 mV/°C). These temperature readings are input to the fan control software.

The fan control software cycles the fan on and off with a hysteresis of 2°C at the temperature threshold; i.e., at 38°C the fan turns on, and at 36°C the fan turns off. This is valid also in Calibration Mode.

At 50°C, a cabinet temperature alarm occurs that results in the Instrument shutting down.

Table 6-2. Internal Cabinet Threshold Temperatures

Temperature	Action
38°C	Fan ON
36°C	Fan OFF
50°C	Alarm

The fan power driver is located on the Blood Pump Power board; however a motor rate signal from the Blood Pump Controller board determines the input signal for the fan motor.

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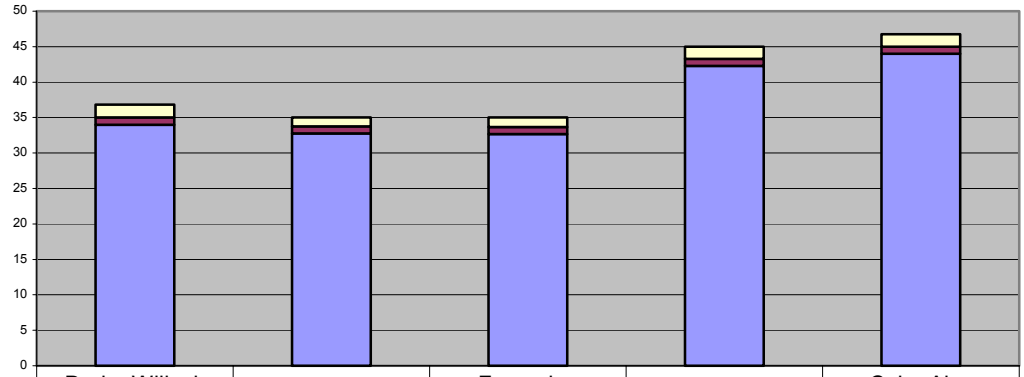
7. DIALYSATE PREPARATION

7.1 DIALYSATE PROPORTIONING

The proportioning ratio used by the Instrument for a particular treatment is determined by the placement of the concentrate lines in Rinse Mode, before starting Self-test and the dialysate selections made in Calibration (Service) Mode.

There are two types of concentrates that can be used in the Arena Instrument: Acetate and Bicarbonate.

- Acetate dialysate proportioning. Acetate proportioning requires 34 parts water to 1 part acetate concentrate. This option may be enabled or disabled by a qualified service technician in Calibration Mode.
- Bicarbonate dialysate proportioning (also known as bicarb). The Instrument may also be set by a qualified service technician to accept a bicarbonate dialysate concentrate from any of five mixing ratios as shown in Figure 7-1. Only one can be chosen at any one time. The Drake Willock proportioning is selected by default, requiring 34 parts water to 1 part acid concentrate to 1.83 parts of bicarbonate concentrate, containing sodium chloride (NaCl) and sodium bicarbonate ($NaCHO_3$) in the bicarbonate concentrate.



	Drake Willock (36.83X)	Fresenius (35X)	Fresenius (French) (35 X)	Cobe (45X)	Cobe Ajax (46.75X)
Bicarb	1.83	1.225	1.34	1.72	1.75
Acid	1	1	1	1	1
Water	34	32.775	32.66	42.28	44

Figure 7-1. Acid/Bicarbonate Concentrate Formulations

The Single Board Computer (SBC) determines whether to proportion for acetate or bicarbonate during the Rinse Mode by

reading the “A” and “B” concentrate port interlock information. Proximity sensors on the “A” and “B” concentrate ports relay the information on whether the “A” and “B” concentrate fittings are in their respective ports. When the concentrate connector is in the rinse fitting, a pulsed infrared LED signal reflects off the concentrate connector onto a phototransistor in the other portion of the proximity sensor. This information is relayed through the I/O Hydraulic Power board and the I/O Controller to the SBC. Upon successful completion of Self-test, the concentrate treatment mode is set for the remainder of the dialysis treatment. In order to change between acetate (if enabled) and bicarbonate dialysis, the Instrument must be in Rinse Mode.

- The Instrument will perform an acetate dialysis if acetate is enabled, the A concentrate line (pink connector) is removed from the concentrate interlock, and the B concentrate connector (blue connector) remains attached to the interlock. If acetate is not enabled, then the Instrument will always run bicarbonate, regardless of which interlocks are open.
- The Instrument will always perform a liquid bicarb dialysis if both the A and the B concentrate lines are removed from the concentrate interlock.
- If both the bicarbonate and powder (dry bicarbonate) concentrate lines are open, the Instrument will alarm (only for the dry bicarbonate option).
- The Drake Willock proportioning ratio is not compatible with the powder option. (See Section 24, Powder Bicarbonate.) One of the alternate proportioning ratios listed in Figure 7.1 must be used for powder bicarbonate dialysis
- If a Cobe formulation has been selected, the proportioning ratio is for Cobe bicarbonate only, regardless of the concentrate line placement. No acetate proportioning is allowed.

7.2 SODIUM AND BICARBONATE PROFILING

Sodium and Bicarbonate Profiling permits the operator to set the sodium and bicarbonate levels for the entire treatment. The sodium and bicarbonate levels are changed in adjustable time increments (15, 30 or 60 minutes) throughout the dialysis treatment. The maximum and minimum sodium and sodium bicarbonate levels are set by the technician in Customize Mode using the Customization / Calibration screen. The conductivity alarm limits automatically set around the expected conductivity at the adjusted values.

When the Rinse Mode is started, the adjusted sodium and bicarbonate values automatically set to the standard bath values.

If the sodium profiling is used after the sodium level was adjusted using the SET ADJUSTED SODIUM button and keypad, the profiling information will override the previously set adjusted value. Similarly a SET ADJUSTED SODIUM button and keypad entry will override a previously set profile.

If the bicarbonate profiling is used after the bicarbonate level was adjusted using the SET ADJUSTED BICARB button and keypad, the profiling information will override the previously set adjusted value. Similarly a SET ADJUSTED BICARB button and keypad entry will override a previously set profile.

If the sodium or bicarbonate level is adjusted during the Dialyze Mode, the level will change to the new adjusted value when the keypad ENT button is touched.

7.3 VOLUMETRIC PROPORTIONING SYSTEM

7.3.1 Overview

The Instrument's volumetric proportioning system consists of fixed volume pumps for concentrates and a fixed volume metering device for dialysate. The concentrate pumps and metering device are linked electronically through the UF-Proportioning controller to provide a fixed ratio proportioning system. The pumps can change the speed to set values to match changes in the flow rate, the programmable sodium and bicarbonate profiles, the sodium button and the concentrate selection. Refer to Figure 7-2, Hydraulic Diagram.

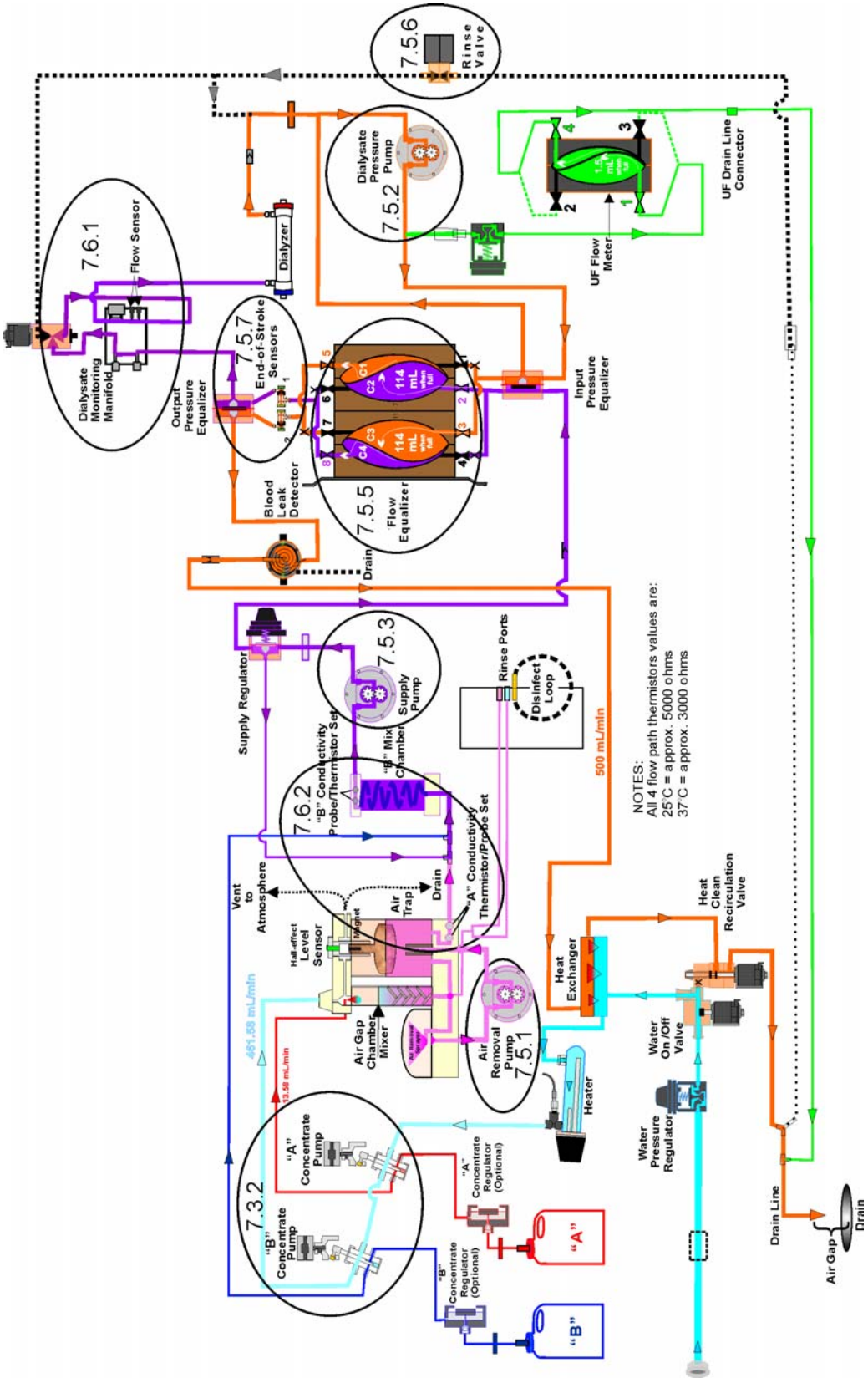


Figure 7-2. Hydraulic Diagram

Using the dialysate flow rate and the concentrate information, the Instrument calculates the amount of concentrate(s) required per stroke of the flow equalizer. The rest of the flow equalizer volume is filled with water. Figure 7-3 illustrates the Drake Willock dialysate option.

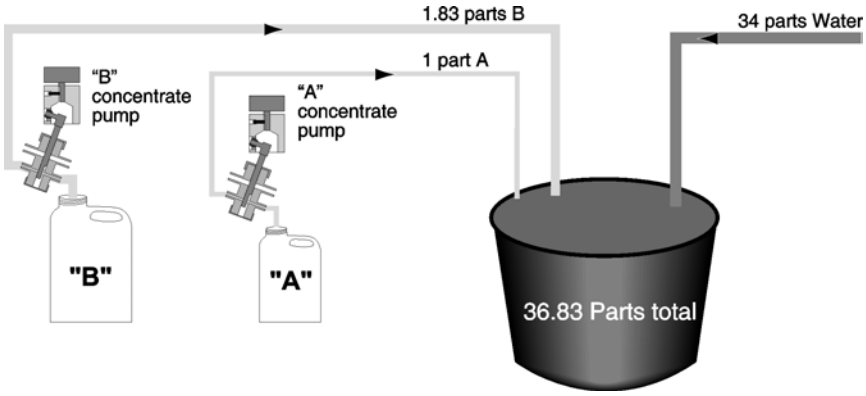


Figure 7-3. Basic (36.83X) Volumetric Proportioning

Imagine a bucket that holds exactly 36.83 mL. For a Drake formulation, the "A" concentrate pump delivers 1 mL of acid concentrate. The "B" concentrate pump delivers 1.83 mL of bicarbonate concentrate. Filling the rest of the bucket with 34 mL of water completes the proportioning of the dialysate.

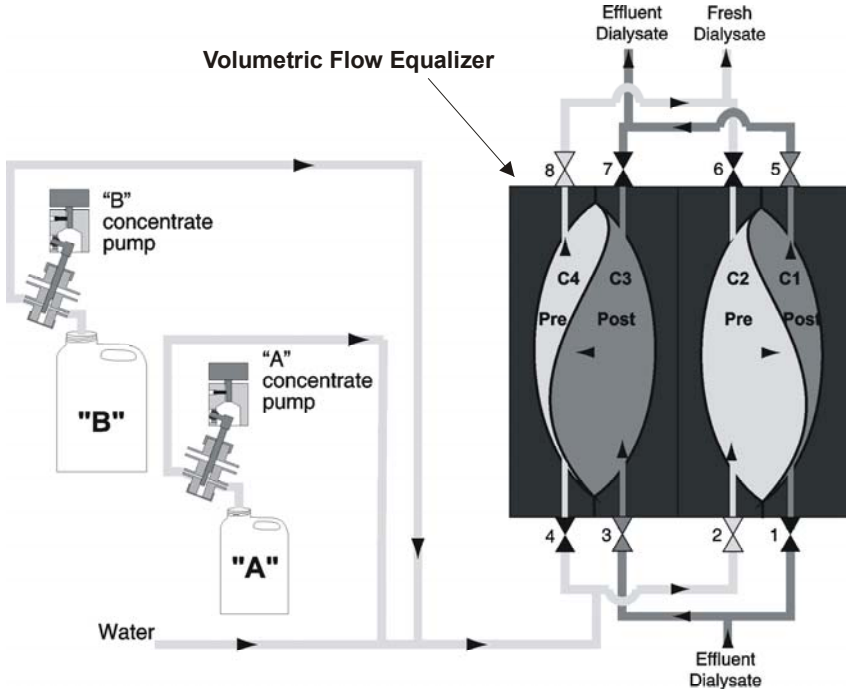


Figure 7-4. Arena Volumetric Proportioning

Instead of the bucket, the water volume is measured by the volumetric flow equalizer. This volumetric flow equalizer fills with a very precise volume of fluid and the Instrument knows this volume. Based on the flow rate and the concentrate type, the Instrument calculates the amount of the acetate or acid and bicarbonate required per stroke of the flow equalizer. The rest of the flow equalizer volume is filled with water resulting in a properly proportioned dialysate.

7.3.2 "A" and "B" Concentrate Reciprocating Rotating Piston Pumps

The acid (or acetate for acetate dialysis) concentrate is pumped from its container into the air gap chamber through a fixed volume reciprocating rotating piston pump called the "A" concentrate pump and the pink concentrate line.

The bicarbonate (or a mixture of acetate and water recirculated in acetate dialysis) concentrate is pumped from its container through another fixed volume reciprocating rotating piston pump called the "B" concentrate pump, and the blue concentrate line.

These pumps are controlled by a stepper motor that is automatically adjusted to turn a precise number of rotations per minute. The pump delivers a fixed volume of concentrate each revolution. The motor is coupled to the piston of a precision ceramic pump. As the piston rotates it moves in and out of the cylinder, alternately drawing in fluid through one port and discharging it through another port.

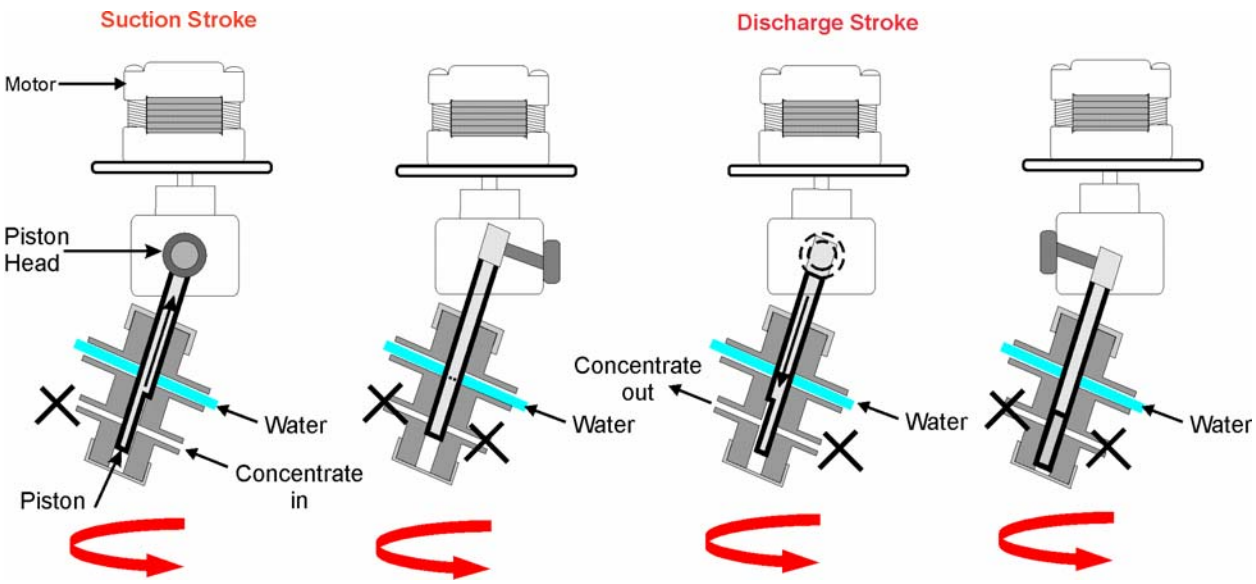


Figure 7-5. Reciprocating Rotating Piston Pump

On the suction stroke, the piston is pulled toward the stepper motor drawing in concentrate. The piston is also rotating as it draws in the concentrate. When it reaches a null point (the end-of-stroke), the flow into the pump is stopped.

The piston continues to rotate until it opens to an outlet into the Instrument. It then pumps concentrate out during the discharge stroke as the piston is pushed away from the stepper motor. The pump continues to rotate and again reaches a null point (end-of-stroke). Then the rotation starts over again.

Two upper ports in the pump are used for water to lubricate the piston. See Figure 7-5.

Both concentrate pumps are protected from particles by a 74-micron filter.

During rinse, the concentrate motor operates at the same ratio as the concentrate formulation to flush concentrate or disinfectant from the concentrate pump chamber. The “A” concentrate line must be attached to the “A” rinse fitting to receive rinse water from this port.

For disinfecting, the “A” concentrate line is attached to the disinfectant rinse fitting and the disinfect line is connected to the disinfect bottle, therefore the “A” concentrate pump delivers disinfectant to the fluid path.

7.4 DIALYSATE PROPORTIONING CONTROL

The UF-Proportioning system controls the concentrate(s) to water proportioning ratios by controlling the dialysate flow rate, and the "A" and "B" concentrate flow rates.

The "A" and "B" concentrate pumps are stepper motor driven piston pumps that deliver a calibrated volume of concentrate per stepper motor revolution (see Section 7.3.2). Their flow rates are controlled by controlling the speed of the stepper motors.

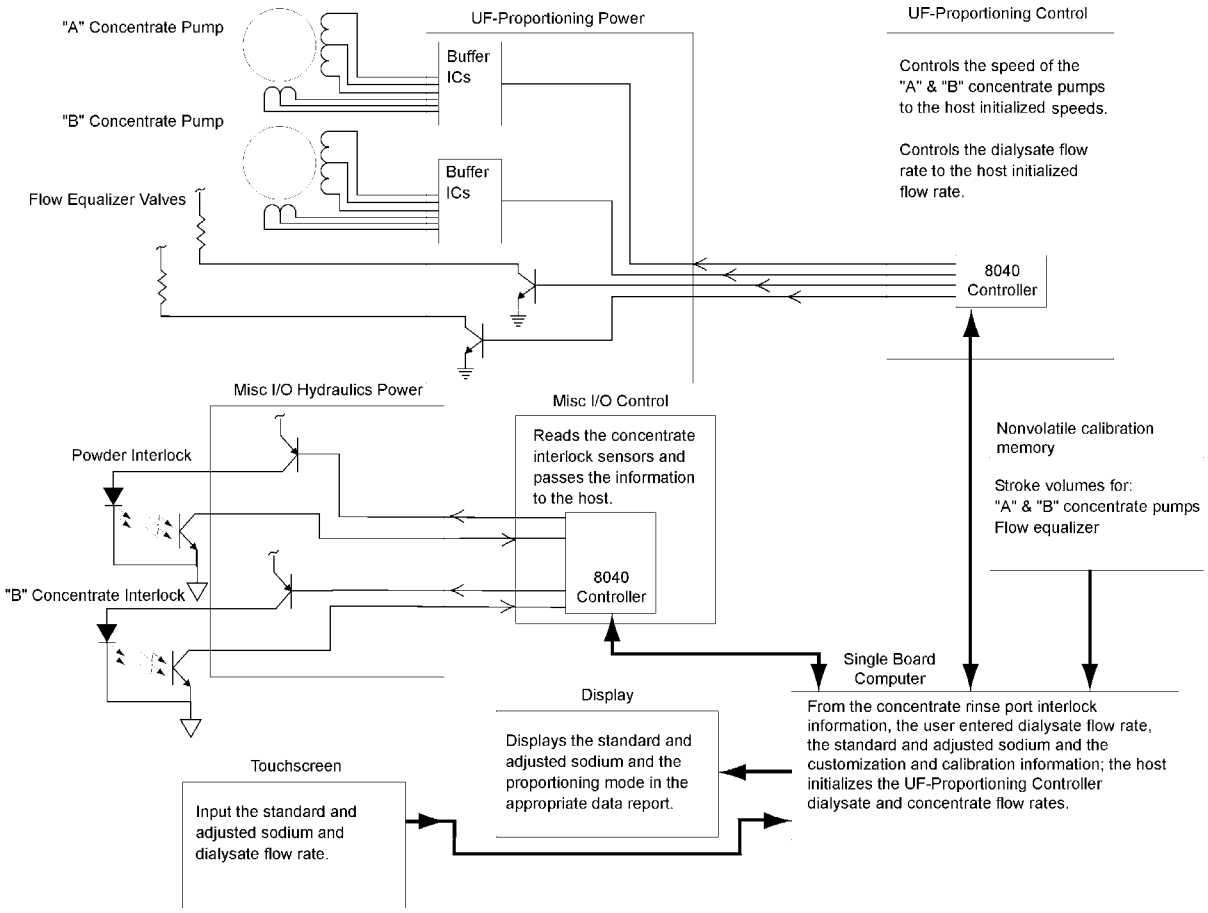


Figure 7-6. Proportioning Control Block Diagram

During the Rinse Mode, the Single Board Computer (SBC) determines the concentrate treatment mode based on the "A" and "B" rinse port interlock information. If the "B" concentrate line is not on the "B" rinse port, a bicarbonate treatment is initiated by setting the proportioning ratios and the conductivity alarm limits appropriately. Conversely, if the "B" concentrate line is in the "B" rinse port, an acetate treatment is initiated. The Powder Interlock is used only with the Powder Bicarbonate Option (see Section 24).

Using the dialysate flow rate, sodium and bicarbonate profiles, sodium button and the proportioning ratios, the SBC determines the associated concentrate flow rates and stores the two concentrate pump speeds in the UF–Proportioning controller.

The 4-phase, 100-step/rev stepper motors used in the concentrate pumps are driven in a 2-phase bidirectional mode. This drive was implemented on the UF-Proportioning Power board utilizing a dual full bridge driver for each motor. Since two inverters are also included on the board, only two clock signals are required to step each motor. These motors are driven from an independent power supply developed on the UF-Proportioning Power board so that various motor voltages can be accommodated by adjusting the power supply level. Inductive currents developed by the motors are dissipated through a Shottky diode array IC on the UF-Proportioning Power board.

7.5 DIALYSATE FLOW CONTROL

The Instrument flow path contains three pumps: a deaeration pump, a dialysate pump, and a supply pump.

7.5.1 Deaeration Pump

The deaeration (or air removal) pump runs at a constant speed for all flow rates. This speed is set in the calibration mode so that a deaeration pressure of approximately –500 to -650 mmHg in the air removal sprayer chamber (deaeration sprayer) is achieved. The deaeration pump is situated in the flow loop with the deaeration sprayer (directly after the "A" mix point) to produce a low pressure that removes the dissolved air in the water being prepared as dialysate.

7.5.2 Dialysate Pump

The dialysate pump operates at a different but constant speed depending on each of the dialysate flow rates. This pump runs at about 1500 mL/min, when the dialysate flow is set to 500 mL/min. The speed at which it operates is proportional to the dialysate flow rate. Therefore its lowest speed is at the 300 mL/min dialysate flow rate and its highest speed is at the 1000 mL/min dialysate flow rate. The dialysate pump is in the postdialyzer flow circuit and provides the pressure, which draws the fluid from the dialyzer and delivers it to the flow equalizer. This pump has a recirculation flow path around it so that the flow through the pump remains constant even though the flow equalizer flow is pulsatile.

7.5.3 Supply Pump

The supply pump speed can continually adjust throughout operation. Its speed is calculated at each flow equalizer stroke so end-of-stroke times of one second are achieved. See Figure 7-7.

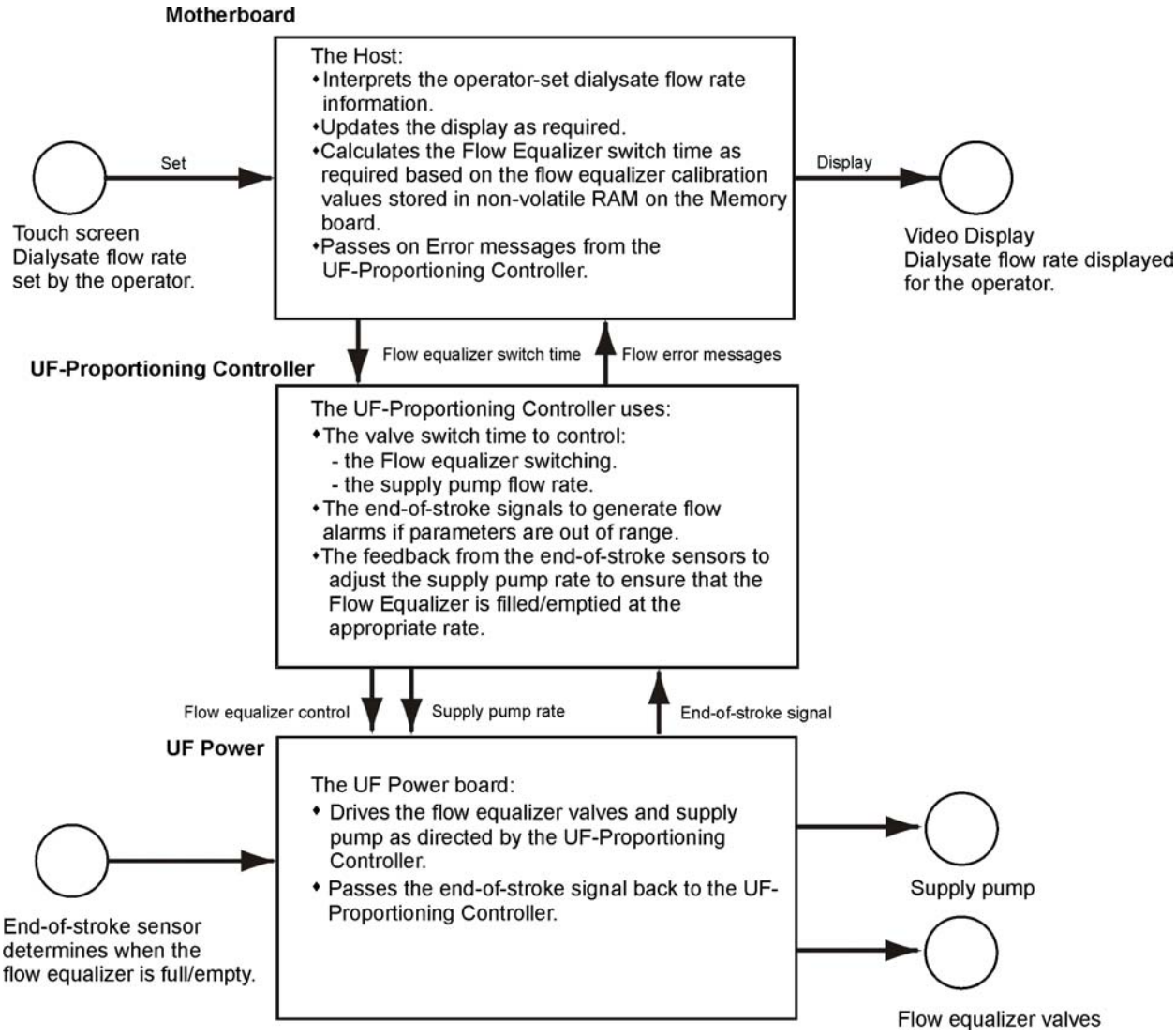


Figure 7-7. Dialysate Flow

The UF-Proportioning system controls the dialysate flow rate by controlling the time between the switching of the flow equalizer (which has a fixed volume) valves provided that all the fluid within the flow equalizer chambers has been exchanged.

The supply pump speed controls the instantaneous dialysate flow rate, so the UF-Proportioning controller controls the supply pump speed in order to maintain a consistent end-of-stroke time. If end-of-stroke is not sensed, the Instrument waits only 15 seconds after

the time it expects the end-of-stroke signal and then switches the flow equalizer valves (secondary flow equalizer time-out).

To ensure a complete volume transfer in the flow equalizer, flow sensors (end-of-stroke sensors) have been placed in the flow path to sense when the flow stops (end-of-stroke). The valves will not switch before the end-of-stroke condition is sensed unless a secondary time-out condition is encountered. Since the speed of the supply pump determines the instantaneous dialysate flow rate, it is controlled so that both end-of-stroke signals are received in a predefined amount of time before the desired valve switch time. This time is fixed and is set to 1 second upon initialization.

The average flow equalizer volume is calibrated (measured) in the Calibration Mode. The time between the switching of the flow equalizer valves is scaled by the SBC according to the calibration constant and stored in the UF-Proportioning controller so that the desired dialysate flow rate is achieved.

7.5.4 Pump Drive Circuitry

The drive circuitry for the three flow pumps is embedded in each of the associated pumps. Each pump is supplied with unregulated nominal +24 VDC, ground, and a control voltage. Each pump produces a tachometer signal that is sent back to the UF-Proportioning Power board. This signal is used by the UF-Proportioning controller to control the long-term speed variations of the flow pumps.

7.5.5 Flow Equalizer Drive Circuitry

The flow equalizer valve drivers on the UF-Proportioning Power Board conduct the current which powers the eight flow equalizer valves. The current typically averages about 1.5 A at 50% duty cycle with a period range of 6.7 to 22 seconds depending on flow.

There are flyback diodes on the same board which conduct current each time the associated flow equalizer valve set is de-energized.

7.5.6 Dialysate Pressure Relief (Rinse) Valve

This valve prevents a vacuum build-up in the flow path when the connectors are on the rinse block during Prime and Rinse Mode. It is also opened during Rinse and Self-Test Modes except during UF tests.

The dialysate pressure relief valve driver, on the UF-Proportioning Power Board, conducts the current which powers this valve.

7.5.7 End-of-stroke Sensors

Flow detection is accomplished by an optical sensor. For more information on this sensor, refer to Section 4, Hydraulic Theory.

7.6 CONDUCTIVITY MEASUREMENT AND MONITORING

Conductivity is used as a measurement of the electrolyte composition of the dialysate. The hardware for measuring conductivity is always a cell for measuring changing resistance as the amount of dissolved salt changes and a thermistor for measuring temperature changes. Electronic circuits are used to equate these changing resistances to the standard measuring conditions of a 1 cm cell at 25 Celsius. The information from these devices can be used to give us conductivity in the units of milliSiemens/cm (mS/cm) @ 25°C.

The Flow Equalizer and the concentrate pumps control the dialysate composition, therefore controlling the conductivity.

Conductivity redundancy involves three conductivity probes communicating with two electronic systems: UF-Proportioning and I/O systems. Each of these systems involves separate control and power.

7.6.1 Conductivity Measurement

Conductivity is measured by the Input/Output system. Measurement consists of a primary conductivity probe positioned just prior to the bypass valve, in the dialysate manifold. The primary probe's conductivity is used for primary alarms and the displayed conductivity.

The primary probe uses an AC signal with local temperature compensation. The signal from the primary probe is amplified, rectified and buffered on the I/O Hydraulics Power board. The resulting signal is sent to the A/D converter on the I/O Controller. The microprocessor on the I/O Controller applies conductivity and temperature calibration factors and compares the resulting value to the primary alarm limits. An alarm message is passed to the SBC operating software if necessary. The conductivity value is also passed to the SBC software for display on the LCD.

7.6.2 Conductivity Monitoring

Conductivity is monitored by the UF-Proportioning System. This monitoring consists of the following:

- An acid (or acetate) conductivity probe (referred to as the “A” conductivity probe) which is used to monitor that the acid and water were mixed correctly. This probe is located in the supply manifold.
- A bicarbonate conductivity probe (referred to as the “B” conductivity probe) which is used to monitor that the addition of bicarbonate concentrate increased the conductivity of the dialysate by an appropriate amount. This probe is located in the “B” mix chamber.

The “A” and “B” conductivity probes are used for A & B alarms, and for proportioning verification. Each of these probes utilizes an AC signal and local temperature compensation to provide the required accuracy and confidence.

The acid and bicarbonate conductivity probe signals are amplified, rectified and buffered on the UF-Proportioning Power board. The resulting signal is sent to the A/D converter on the UF-Proportioning Controller board. The microprocessor on the UF-Proportioning Controller board applies conductivity and temperature calibration factors to the conductivity and compares the value to the alarm limits. If the value is outside the alarm limit, an alarm is passed to the host software on the SBC. The SBC software generates the system actions (bypass, audio alarm, alarm lamp etc) if an alarm is generated. The value is also passed to the host software for display in the conductivity data report. Refer to Figure 7-8.

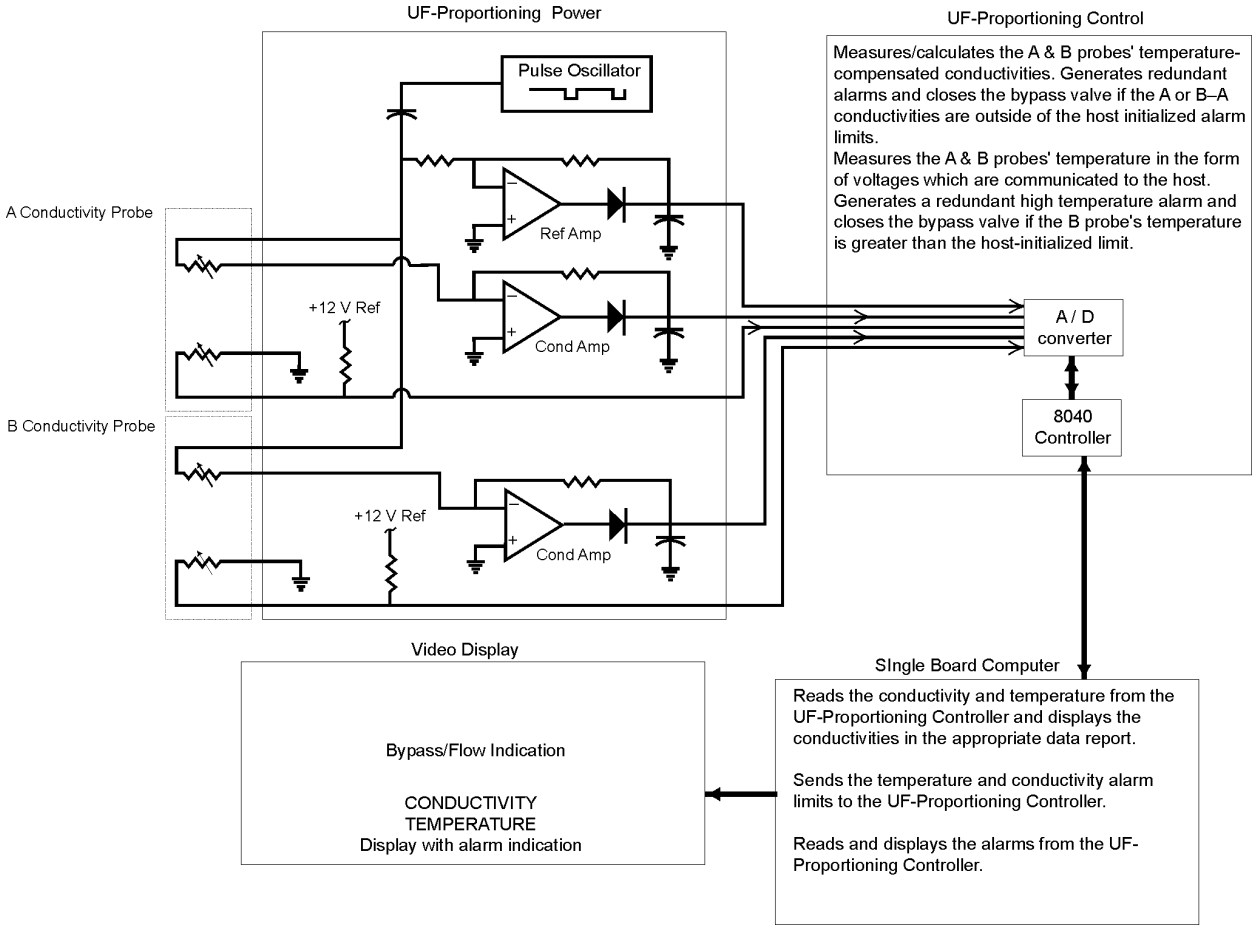


Figure 7-8. UF-Proportioning Temperature / Conductivity Block Diagram

7.6.3 Conductivity Calibration

Refer to Section 18, Calibration/Adjustments, for the actual calibration procedure.

The conductivity probes are calibrated in the Calibration Mode. The resistance of each probe is measured at a known conductivity and temperature (by the use of an external reference meter) for the scaling of the probe's base resistance in the outlet relationship. During the calibration, when the primary conductivity is stable, the three conductivities are set equal to an independent conductivity reference meter through the use of the three programmable gain constants contained within the two controllers.

The conductivity is measured by the controllers using circuitry which measures an AC resistance between each pair of the conductivity probe's electrodes. One electrode of each conductivity probe is stimulated with a 1 kHz AC voltage while the other is held at virtual ground (current sense electrode). Two DC voltages are produced by the circuit, one of which is

proportional to the negative peak of the AC stimulation voltage. The other is proportional to the negative peak of the probe's AC current.

The ratio of the voltages is proportional to the resistance of the respective probe. The resistance of the probes has been modeled as a function of temperature and conductivity. Since each of the conductivity probes contains a thermistor, the temperature at each probe is known. The conductivity is calculated using the temperature and resistance readings measured at the probes. The UF–Proportioning system generates alarms from the measured conductivities at the "A" and "B" probes. Since these conductivity alarms are used to verify the proportioning ratios, the alarms are generated by testing the "A" conductivity and the "B" portion of the total conductivity ("B" portion = "B" conductivity – "A" conductivity). The alarm limits are determined from the concentrate treatment mode and are stored in the UF–Proportioning controller by the SBC. Therefore, only during a bicarbonate treatment would the SBC store a non-zero expected "B" conductivity portion.

The UF–Proportioning microcontroller directly deactivates the bypass valve (removing flow through the dialyzer) during a backup conductivity alarm when in the Dialyze Mode.

The UF–Proportioning microcontroller indirectly (via the 8040 microprocessor) triggers an audible and visual alarm.

7.7 CENTRAL CONCENTRATE SUPPLY SYSTEMS

The optional internal concentrate line regulators permit the Instrument to be used with central concentrate delivery systems. Figure 7-2 shows the position of these regulators in the fluid path.

The concentrate surface height of the gravity-feed system must be between 2 feet and 60 feet (0.6 to 18 m) above the Instrument floor level. Pump-driven concentrate supply systems must provide concentrate to the Instrument at 1 to 30 psi (52 to +1560 mmHg).

To provide the optimum performance, the preferred range for gravity-feed systems is 2 to 20 feet (0.6 to 6 m) and for pump-driven systems is 1 to 10 psi (52 to 520 mmHg). In addition, the concentrate flow rate to each Instrument for a dialysate flow rate of 500 mL/min must be at least 35 mL/min for acid and 60 mL/min for bicarbonate. For a dialysate flow rate of 1000 mL/min the concentrate flow rate must be at least 70 mL/min for acid and 120 mL/min for bicarbonate.

There are connections for three different acid concentrates and one bicarbonate concentrate from the central delivery supply system to the back of the Instrument. These go through the Instrument and directly connect to the supply fittings on the front of the Instrument as shown in Figure 7-9.

In addition to the "A" and "B" concentrate connectors used to connect to concentrate jugs, there are also central concentrate supply fittings are located on the front of the Instrument as shown in Figure 7-9. If concentrate from a central delivery system is used, the concentrate lines are moved to the acid and/or bicarb supply fittings as appropriate.

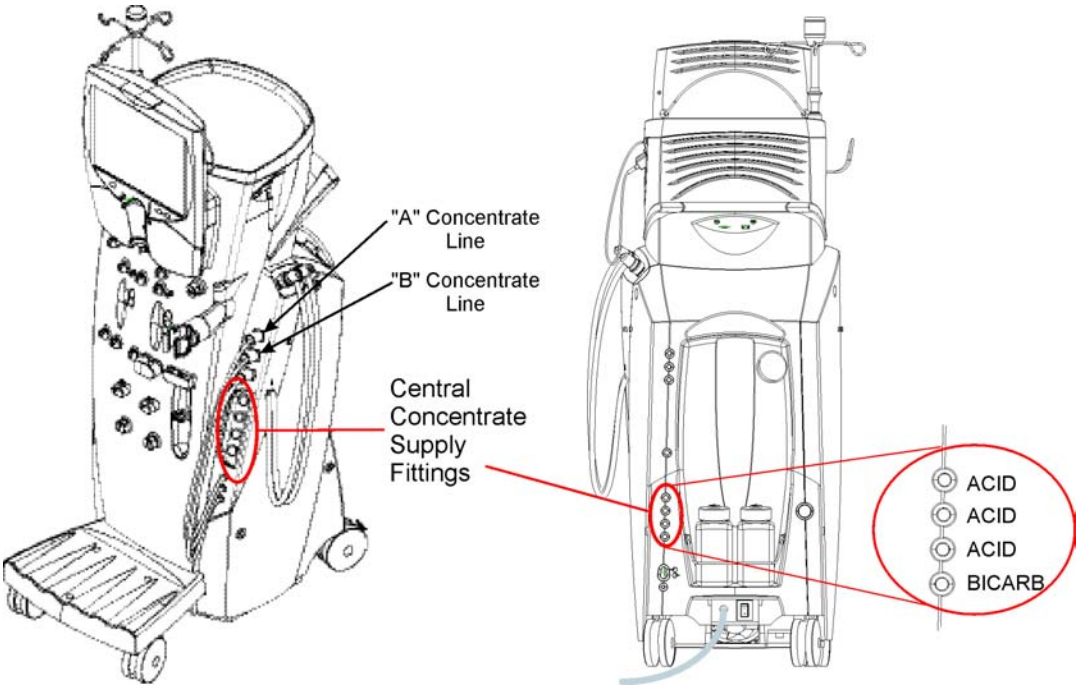


Figure 7-9. Central Supply Fittings on the Instrument

System notes:

- Install a shut-off valve between the concentrate supply and each concentrate connector.
- After installation, the regulator function may be verified by alternately drawing concentrate through the regulator and from a container of the same concentrate (same *manufacturer*, not just the same formulation) and comparing the resulting conductivities.
- The Instrument concentrate line may be lengthened up to 10 feet (3 m). The extended line segment must be connected between the concentrate line filter and the concentrate line fitting (pink or blue). The extended line segment should be the

same type of tubing used in the standard concentrate line (part number T010500).

WARNING

Instrument concentrate lines longer than standard will affect the effectiveness of the heat clean and chemical disinfection cycle.

CAUTION

It is essential that all central concentrate supplies be equipped with a manual shut-off valve at each Instrument position. These shut-off valves are required to prevent leaking when service is performed on the concentrate regulator or trunkline. These valves also prevent leakage when the female fitting shut-off does not completely seal.

- In large branching distribution systems, the concentrate velocity is relatively slow at the ends where there are few Instruments drawing from the concentrate supply. It is important that the branch lines be of diameters consistent with the expected flow rate. If this is not done, air purging and concentrate change may be excessively slow.
- In pump-driven concentrate supply systems, there should be a return line from the end of each branch to the supply pump to facilitate rapid concentrate movement.
- In gravity-fed systems, this can be accomplished by means of manual valves fitted at the far end of each distribution branch line.
- The central concentrate supply should be disinfected periodically. Refer to your clinic's procedures. It is important to culture frequently and identify the organisms so that the best means and schedule of disinfection may be prescribed.

WARNING

The concentrate lines from the central supply to the optional panel mount fittings are NOT part of the Instrument disinfection fluid path. These lines must be disinfected by the methods used for the central concentrate supply system.


Arena

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Arena

8. ULTRAFILTRATION

8.1 OVERVIEW

The Arena Instrument accurately controls fluid removal. A volumetric flow equalizer controls and balances dialysate to and from the dialyzer. The volume of fresh dialysate measured and delivered to the dialyzer by the predialyzer side of the flow equalizer is equal to the volume of used dialysate removed from the dialyzer by the postdialyzer side of the flow equalizer. In the following discussion and graphics, the terms "predialyzer" and "postdialyzer", when referring to one side or the other of the Flow Equalizer, will be shortened to "pre" and "post".

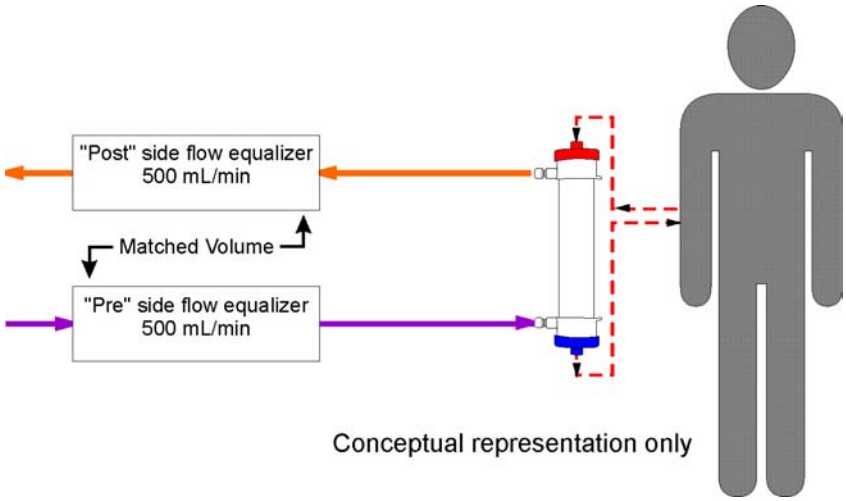

Figure 8-1. Volumetric Control

Between the balanced "pre" and "post" flow equalizer compartments are two openings. One is the dialyzer membrane surface; the other is the UF flow meter. The UF flow meter is controlled by the UF-Proportioning Controller board to remove a known or calibrated amount of spent dialysate from the dialysate compartment. The fluid removed by the UF flow meter causes an identical amount of fluid to be removed from the blood side of the dialyzer. Since the flow equalizer balances the dialysate flowing to and from the dialyzer, the fluid going through the UF flow meter is equivalent to the ultrafiltrate removed from the patient

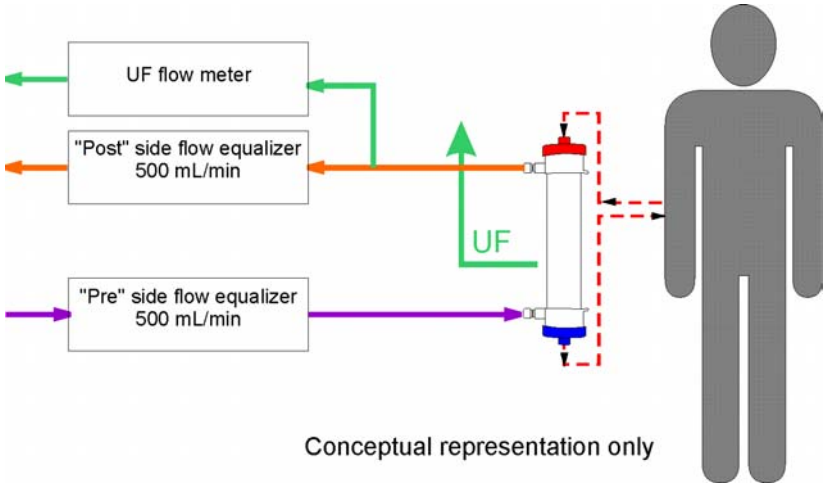

Figure 8-2. UF Flow Meter

The flow through the UF flow meter is displayed in the UF RATE window. The fluid that passes through the UF flow meter is not entirely ultrafiltrate. It is volumetrically equivalent to the patient's ultrafiltrate. The total volume of fluid removed from the patient is continuously displayed throughout the treatment in the UF REMOVED window.

8.2 UF REMOVAL

The UF–Proportioning system controls the UF removal rate by controlling the time between the switching of the UF removal metering device valves. The UF-Proportioning system controls the accumulated UF volume by counting the number of UF removal meter strokes.

Since the UF removal metering device volume is calibrated in the Calibration Mode (Section 18, Calibration / Adjustments), the rate which the host (Pentium microprocessor) passes to the UF–Proportioning controller (number of seconds between valve switches) is scaled so that the UF removal rate entered by the user is achieved.

The UF removal volume entered by the user is scaled by the UF metering device's stroke volume to a number of UF meter strokes. The host passes the number of UF meter strokes to the UF-Proportioning controller. The UF-Proportioning Controller will then control the UF-Proportioning Power board to switch the UF removal meter valves and decrement the stroke number, at the desired rate, as long as the stroke number is greater than zero. The Host can then calculate the UF removal volume accumulated by subtracting the number of UF strokes remaining, scaled by the stroke volume, from the operator entered desired UF removal volume. The accumulated volume is displayed during the Dialyze

Mode. This value remains during the Rinse Mode and is cleared upon the entry of the Self Test Mode.

In Rinse Mode, the UF removal rate is 3.6 L/h and the screen indicates no UF volume accumulated. During the Self Test Mode, no UF removal occurs except for during specific self tests performed by the Instrument (no UF volume is accumulated). In the Prime Mode, the UF removal rate is set by the operator and is no greater than the service technician-set maximum UF rate (no UF volume is accumulated). During the Dialyze Mode and while the blood pump is running, the UF removal rate is set by the operator and is limited to the range between the lower (0.00 to 1.00 L/h) and upper (1.00 to 4.00 L/h) limits set by the service technician.

For UF removal to occur in the Dialyze Mode the following conditions must be met:

- A target UF volume and a UF rate have been entered (or treatment time and target UF volume have been entered and a UF rate calculated by the Instrument is used).
- The blood pump is pumping.
- The target UF volume has not been reached (or a manual UF rate is set, or the minimum UF is greater than the calculated UF).

The UF–Proportioning Power board is used to drive the UF removal valves.

8.3 DESCRIPTION

The primary hydraulic components of the UF system are the Flow Equalizer and the UF flow meter.

The Flow Equalizer controls the ultrafiltration to zero by balancing the flow to and from the dialyzer, making sure that fresh and spent dialysate are introduced and removed in equal volumes from the dialyzer.

Ultrafiltration is controlled by the UF flow meter, using a diaphragm chamber to displace the ultrafiltrate volume. The only place the ultrafiltrate can come from is across the dialyzer membrane.

Refer to Figures 8-3, 8-4 and 8-5 for the location of the components in the Instrument and a simplified hydraulics diagram.

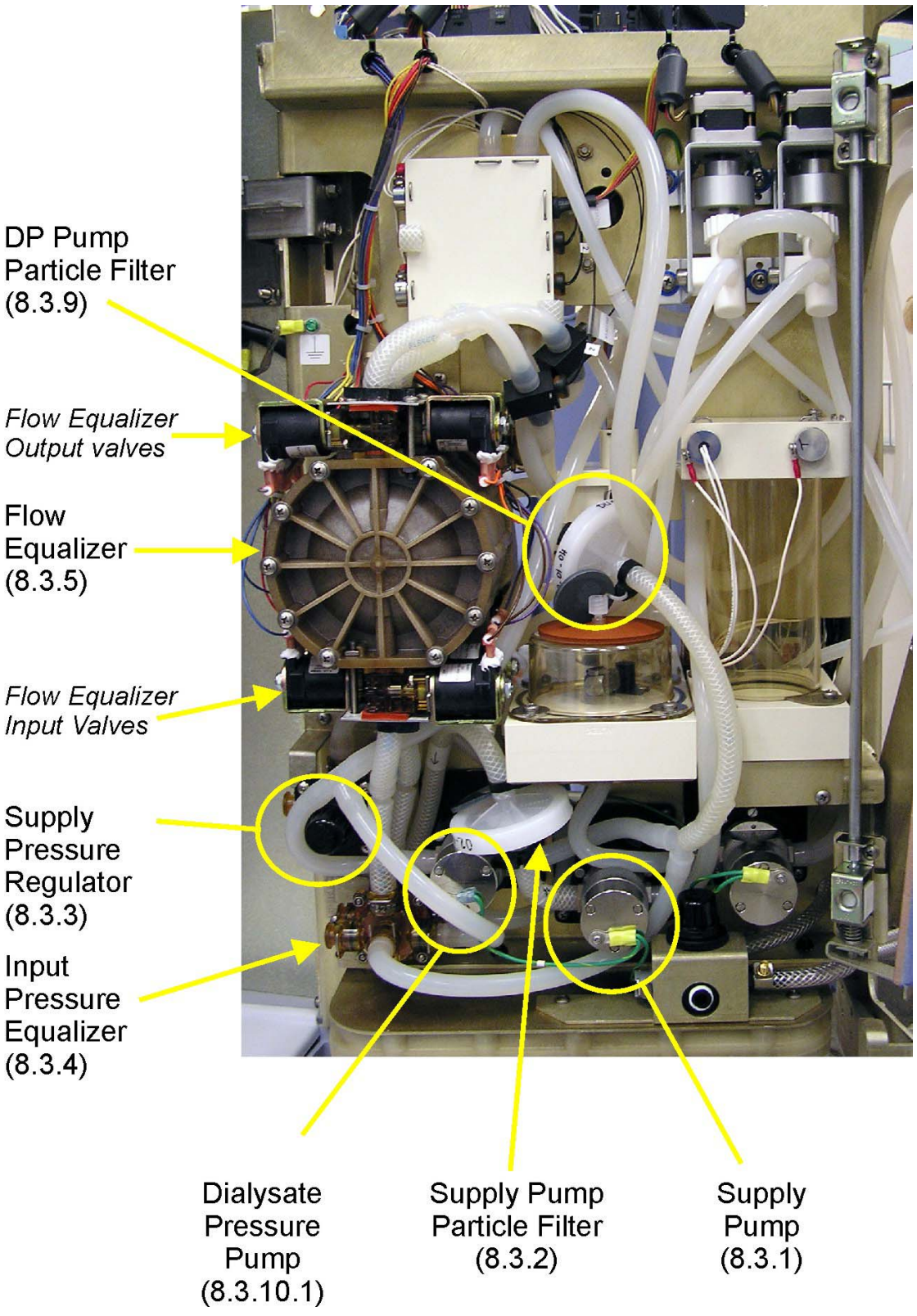

Figure 8-3. Hydraulics Module, Front Side

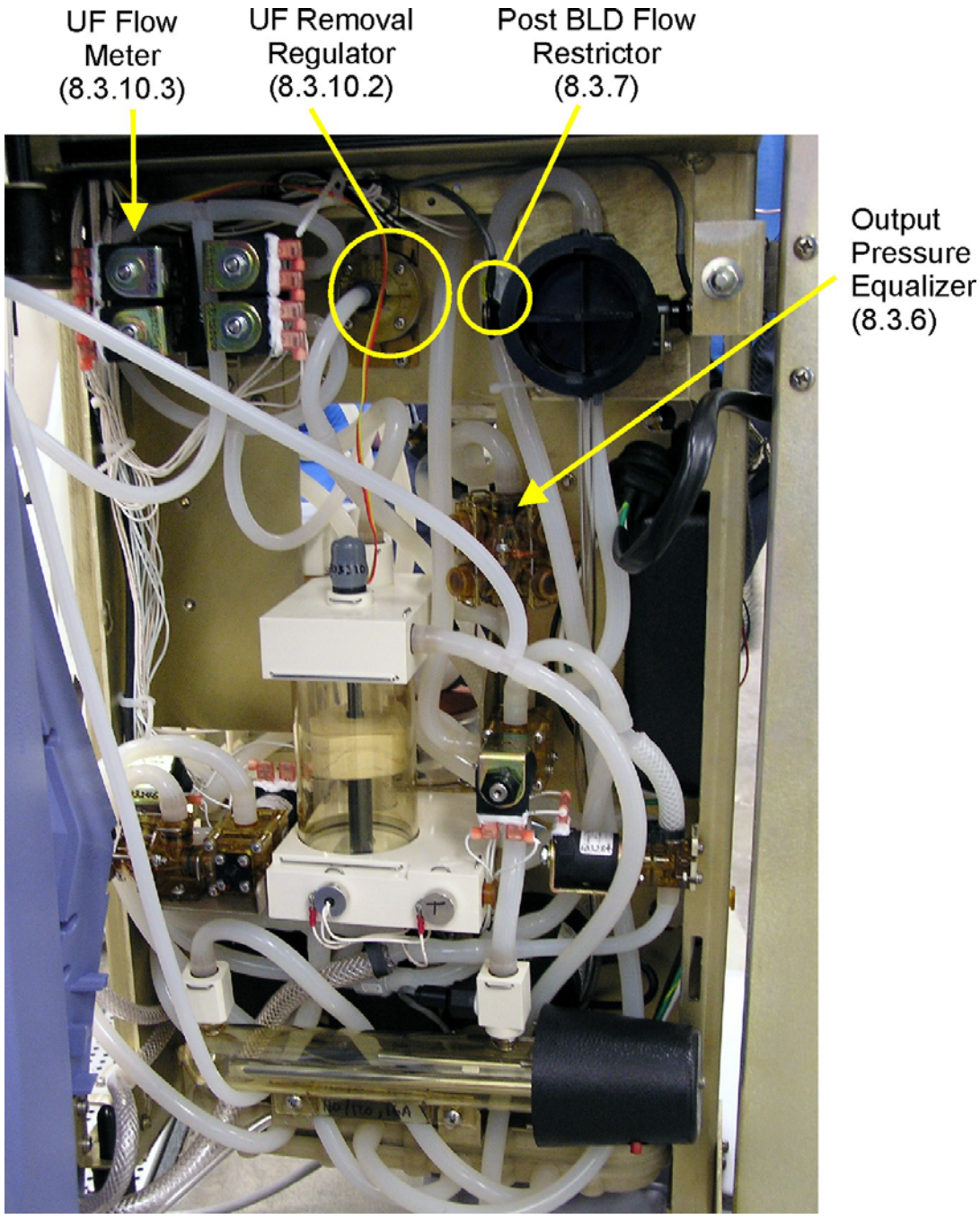

Figure 8-4. Hydraulics Module, Back Side

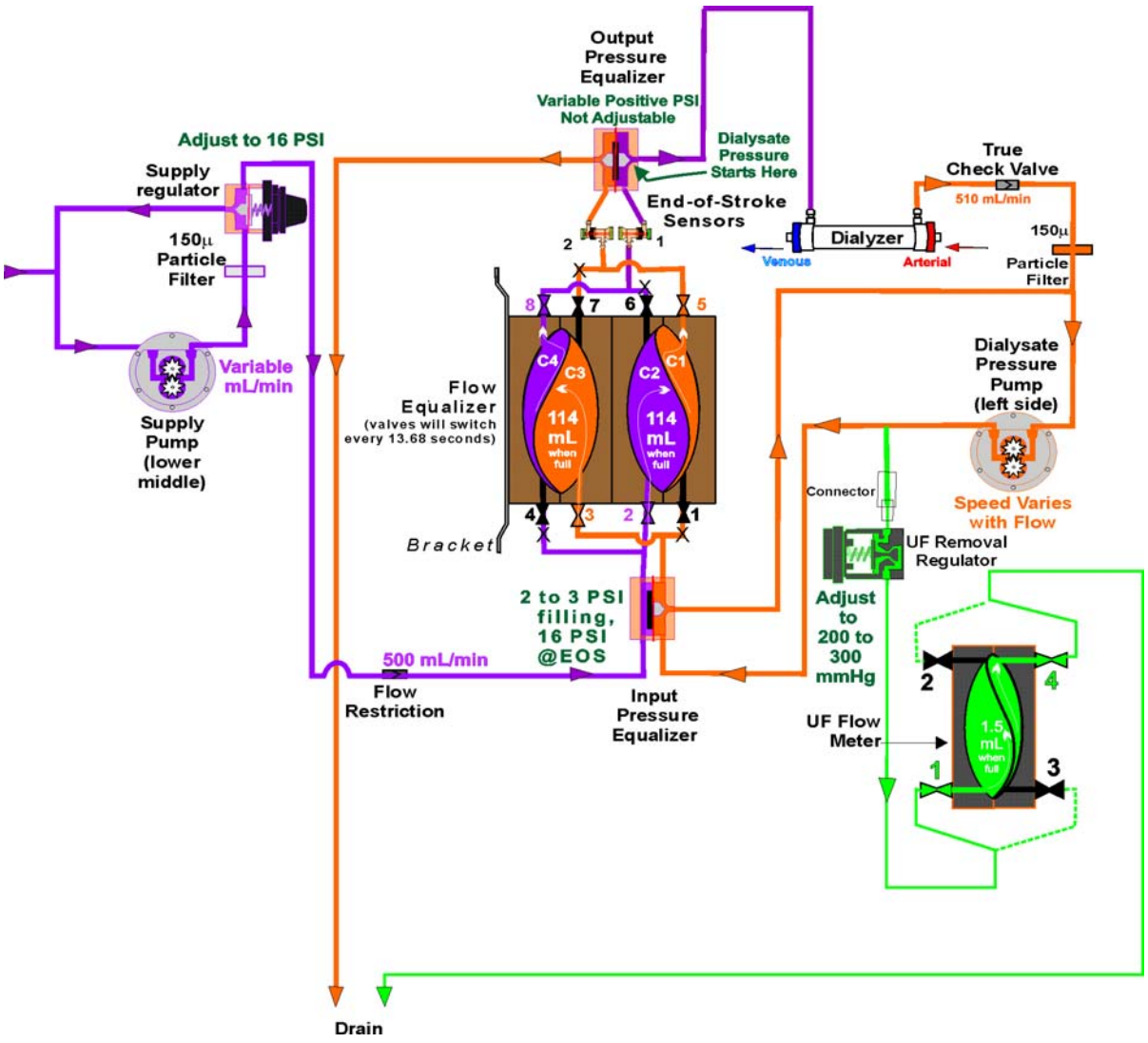

Figure 8-5. Ultrafiltration System Flow Diagram

Note

For clarity purposes, this hydraulic diagram is simplified and does not show the" B" Mix Chamber in the Supply Pump Recirculation Loop, the Dialysate Manifold and Bypass Valve between the Output Pressure Equalizer and the dialyzer, the Blood Leak Detector after the Output Pressure Equalizer, and the Flow Equalizer. Please refer to the drawing at the end of Section 4, Hydraulic Theory, for greater detail.

8.3.1 Supply Pump

The supply pump fills the fresh dialysate side of the flow equalizer with fluid. The supply pump pumps at a rate slightly higher than the dialysate flow rate set by the operator. This extra flow ensures an adequate supply of solution to fill the flow equalizer. The extra fluid is looped back to the pump inlet via the supply regulator. For

more information on the speed control of the supply pump, refer to Section 7, Dialysate Preparation.

8.3.2 Particle Filter ("Post" Supply Pump)

This filter traps particulate matter larger than 150 microns upstream of the supply pressure regulator. Particulate matter in the flow equalizer and UF flow meter can cause ultrafiltration errors.

The service life of the particle filters depends on the rate at which material collects on the filter screens, increasing the filter pressure drop. Ultimately, the performance of the Instrument may be affected.

If filter clogging is due to precipitation of dialysate in the fluid path, the filters must be replaced as part of the fluid path cleaning process.

Refer to Section 16, Preventive Maintenance, for a recommended routine maintenance schedule.

8.3.3 Supply Pressure Regulator

The supply pressure regulator controls the peak input pressure to the "pre" side of the input pressure equalizer. When the flow equalizer cavity is filled, the pressure in the pressure regulator increases to its maximum set value (16 psi±1), overcoming the spring force of the regulator spring allowing the dialysate to recirculate back to the “B” mix chamber. The Supply Pressure Regulator is equivalent to an adjustable pressure relief valve.

8.3.4 Input Pressure Equalizer

The Input Pressure Equalizer is located between the outlet of the supply regulator and the inlet of the Flow Equalizer.

The Input Pressure Equalizer matches the input pressures between the "pre" and "post" compartments of the flow equalizer. Matching the pressure across the flow equalizer ensures that the compartments fill at an even rate.

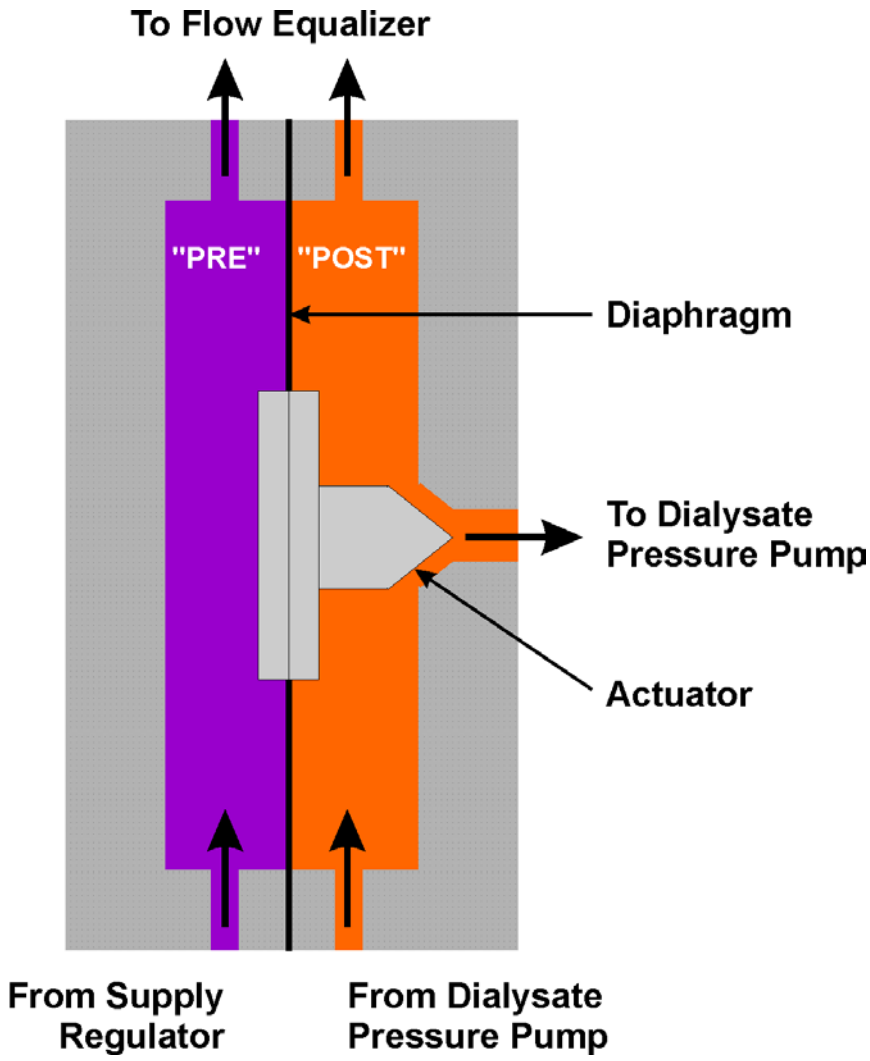

Figure 8-6. Input Pressure Equalizer

The input pressure equalizer is a chamber divided by a flexible diaphragm into two compartments. There is an actuator in the diaphragm on the "post" (spent dialysate) side of the pressure equalizer, which opens or closes a port to the dialysate pressure pump.

The supply pressure regulator pushes the diaphragm on the "pre" (fresh dialysate) side of pressure regulator. When the actuator closes the port on the "post" side of the pressure equalizer, the pressure rises on that side of the pressure equalizer until the spent dialysate pressure matches the supply pressure regulator pressure. By forcing the pressure of the spent dialysate entering the flow equalizer to equal the supply regulator pressure, the flow equalizer fills at an even rate.

8.3.5 Flow Equalizer

The flow equalizer is made of two nearly identical chambers. Each chamber is comprised of two compartments (one predialyzer and one postdialyzer), separated by a diaphragm and four solenoid-actuated valves. These valves control the timing of the filling and emptying of the compartments. The supply pump pressurizes the input to the dialyzer cavity forcing it to fill. By balancing the flow of dialysate to and from the dialyzer, with two flow equalizer compartments, the dialysate flow to the dialyzer can be accurately controlled over a wide range of flow rates.

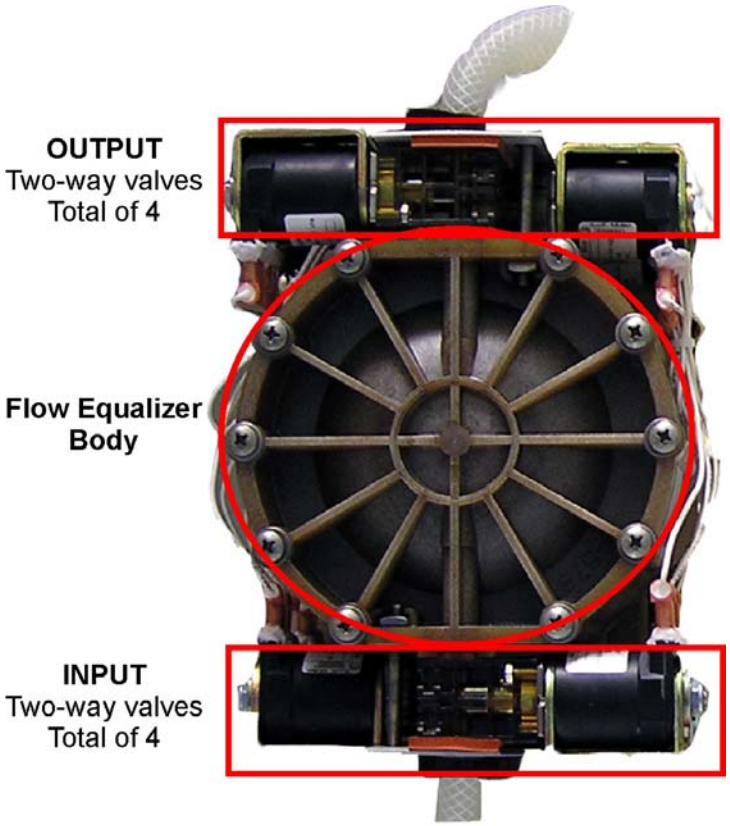

Figure 8-7. Flow Equalizer

The following is a series of graphics and brief descriptions of the three phases of the UF Controller's action on the Flow Equalizer. In each figure, take particular note of the Flow Equalizer's C1, C2, C3, and C4 compartments.

8.3.5.1 Phase 1

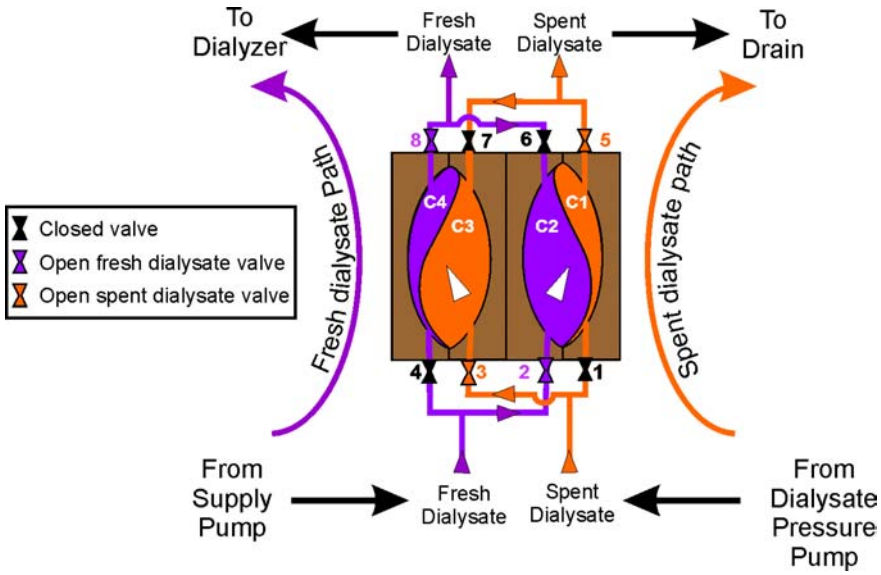

Figure 8-8. Phase 1: Valves 1, 4, 6, and 7 are closed.

While compartment C2 is filling with fresh dialysate, the diaphragm separating it from compartment C1 transverses the cavity, forcing an equal amount of spent dialysate from C1 to the drain. In this cycle, the amount of fresh dialysate entering C2 is equal to the spent dialysate in C1 being displaced. At the same time, spent dialysate enters compartment C3 forcing the diaphragm to transverse the cavity, thereby pushing an equal amount of fresh dialysate out of the compartment C4 to the dialyzer.

8.3.5.2 Phase 2

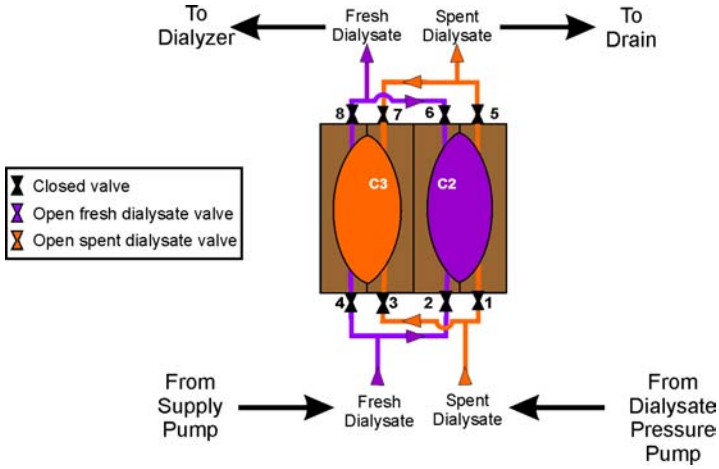

Figure 8-9. Phase 2: All valves are closed.

The solenoid valves which route the flow into and out of the flow equalizer package all turn off for a short period of time (approximately 130 milliseconds). This valve shut-off time helps eliminate any significant effect on ultrafiltration accuracy that

would result from solenoid valves being open at the same time in the same cavity.

8.3.5.3 Phase 3

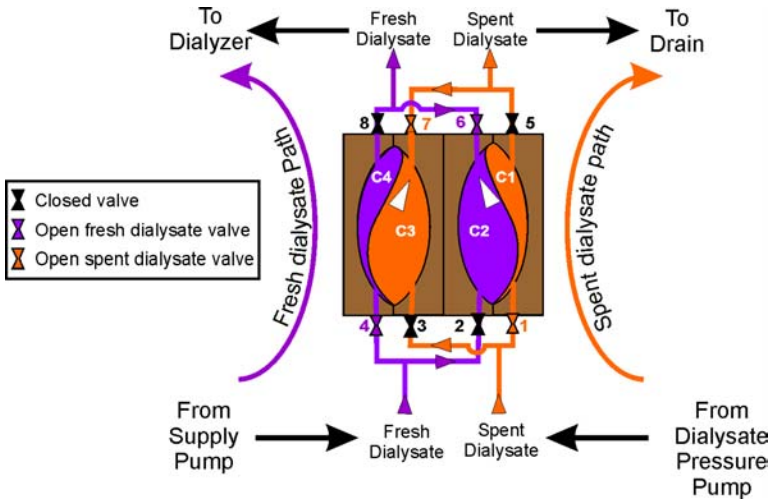

Figure 8-10. Phase 3: Valves 2, 3, 5, and 8 are closed.

This causes compartment C1 to fill with spent dialysate forcing the fresh dialysate in C2 to flow toward the dialyzer. Compartment C4 fills with fresh dialysate pushing the spent dialysate in C3 to flow to the drain. The cycles then begin again with Phase 1.

8.3.6 Output Pressure Equalizer

At the exit of the flow equalizer is another pressure equalizer. Fresh dialysate flows on one side of the output pressure equalizer (PRE) and then goes to the Dialysate Monitoring Manifold; on the other side (POST) spent dialysate leaves the pressure equalizer, going to the Blood Leak Detector and then the drain.

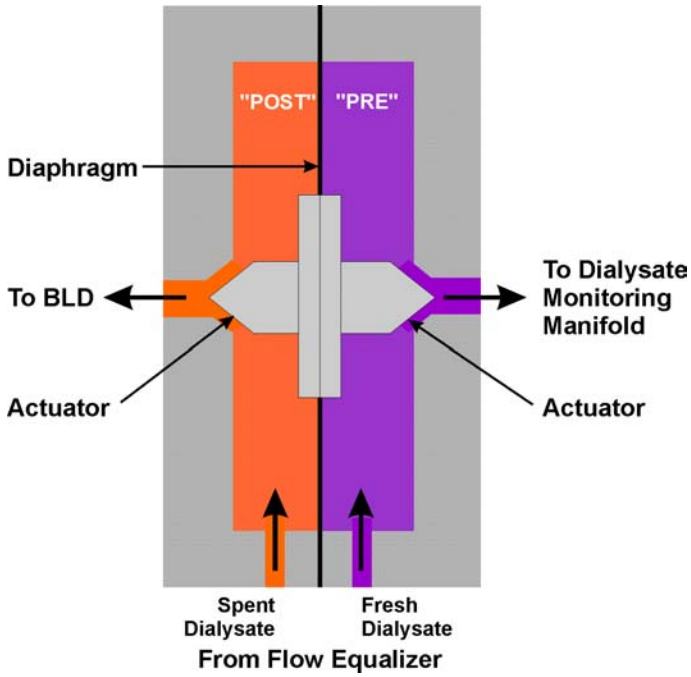

Figure 8-11. Output Pressure Equalizer

This pressure equalizer is also a chamber divided by a flexible diaphragm. At the center and on each side of the diaphragm are two actuators. When the pressure on one side of the diaphragm is greater in relation to the other side, it causes the diaphragm's actuator to close the opening on the side at the lower pressure. With its outlet blocked, incoming fluid increases the pressure until it equals the pressure on the other side of the diaphragm. This forces the actuator to open and normal flow to resume.

If pressure differences were allowed to persist, the flow equalizer cavities would empty at a rate determined by the pressure differences on either side of the flow equalizer. These relative pressure differences could cause uneven filling and make regulation of the flow rate through the dialyzer difficult. By forcing the pressures to equilibrate, the pressure equalizer ensures the flow equalizer chambers empty at an even rate.

8.3.7 Flow Restrictor ("Post" Blood Leak Detector)

A flow restriction on the output of the Blood Leak Detector ensures that there is always positive pressure on the "post" side of the output pressure equalizer.

8.3.8 Dialyzer Connectors and Dialyzer

The dialyzer connectors are used to insert the dialyzer into the UF system. The Instrument can detect if the connectors are connected or are removed from the rinse block. The connectors should be

removed from the rinse block only during Prime and Dialysis Modes. Otherwise an alarm is triggered.

The dialyzer is the source of the ultrafiltrate by allowing the flow of fluid from the patient into the Instrument through the dialyzer membrane.

8.3.9 Particle Filter ("Pre" Dialysate Pressure Pump)

This filter traps particulate matter larger than 150 microns upstream of the dialysate pressure pump. Particulate matter in the flow equalizer and UF flow meter can cause ultrafiltration errors.

The service life of the particle filters depends on the rate at which material collects on the filter screens, increasing the filter pressure drop. Ultimately the performance of the Instrument may be affected.

If filter clogging is due to precipitation of dialysate in the fluid path, the filters must be replaced as part of the fluid path cleaning process.

Refer to Section 16, Preventive Maintenance, for a recommended routine maintenance schedule.

8.3.10 Dialysate Pressure Pump Recirculation Loop

The dialysate pressure pump recirculation loop is located downstream from the dialyzer. It pumps spent dialysate from the dialyzer to the flow equalizer. It also helps equalize the pressure differences in the compartments of the flow equalizer. A third function is to generate the pressure necessary to fill the UF flow meter. This recirculation loop includes:

- dialysate pressure pump (DP pump)
- UF removal regulator
- UF flow meter
- UF drain line connector (sample port)
- input pressure equalizer (refer to Section 8.3.4).

8.3.10.1 Dialysate Pressure Pump

The dialysate pressure pump is located in the dialysate flow path. It operates in a loop that allows it to circulate fluid at a different but constant speed depending on each of the dialysate flow rates. It runs at about 1500 mL/min, when the dialysate flow is set to 500 mL/min. This does not affect the rate of fluid flow past the dialyzer. The DP pump circulates fluid through the dialysate

pressure pump recirculation loop at a rate higher than the rate of flow through the Instrument.

The pressure and flow generated by this pump are to fill and equalize the pressures in the flow equalizer. The DP pump supplies the spent side of the flow equalizer with a mixture of spent dialysate and ultrafiltrate.

8.3.10.2 UF Removal Regulator

The DP pump flow is constrained by the Input Pressure Equalizer, creating a positive pressure that is regulated by the UF removal regulator, which is used to control the filling of the UF flow meter.

This regulator controls the pressure from the DP pump Recirculation loop between 200 and 300 mmHg at the input to the UF flow meter.

8.3.10.3 UF Flow Meter

The UF flow meter is a measuring device composed of a precisely measured chamber with a small diaphragm separating it into two compartments. Each compartment has 2 two-way valves connecting it to either the flow path or the drain. The UF flow meter is connected into the flow path in the dialysate pressure pump recirculation loop, right after the UF removal regulator.

A compartment fills when the UF-Proportioning Power board opens its valve to this positive pressure environment. When one compartment is filling, the second compartment is emptying to the drain. Based on the calibrated volume of the UF flow meter, the UF-Proportioning Controller board can control precise amounts of fluid by sending a calculated number of open/close signals per minute to the valves. The rate of fluid removal is determined by the ultrafiltration information entered into the Instrument by the operator. The Instrument calculates the number of times per minute each valve must cycle to equal this UF volume.

For example:

At an UF rate of 600 mL/hr, 10 mL/min must be removed. Therefore the 1.5 mL UF flow meter compartment is filled (cycled) every 9 seconds.

To summarize, the flow path from the fresh dialysate compartments of the flow equalizer to the dialyzer and back to the spent dialysate compartments of the flow equalizer is a closed system except for two openings. One opening is the dialyzer; the other is the UF flow meter. When the volume in the dialysate pressure recirculation loop is reduced by solution being removed through the UF flow meter, a pressure drop is exerted on the dialyzer.

8.3.10.4 UF Drain Line Connector (Sample Port)

This connector can be open to collect a sample of fluid and measure the UF rate. Refer to Section 18, Calibration / Adjustments, and Section 19, Functional Verification, for more information.

8.4 CONTROL STEPS

1. During Prime, the operator enters the prescribed treatment time (in hours and minutes) in the PRESCRIBED TIME window and the desired fluid to be removed (in liters) in the TARGET UF window.
2. The Instrument automatically calculates the hourly UF rate. The manual UF rate controls the Instrument in the Prime Mode. Once the Dialyze Mode is started, the calculated UF rate is displayed and controls the Instrument.
3. The desired volume of fluid is removed from the patient's blood.
4. The total volume of fluid removed (in liters) is displayed continuously in the UF REMOVED window.

The operator may manually override the calculated UF rate by manually entering the desired UF rate once dialysis has started. The operator may change the prescribed time and/or target UF in the Dialyze Mode if desired.

8.5 PROFILING

The UF Profiling option permits the operator to set the UF rate for the entire treatment. The UF rate is changed at 15, 30 or 60 minute increments throughout the dialysis treatment. The maximum and minimum UF rates are set by the technician.

The UF profile is aborted when the target UF volume is changed, the prescribed time is changed, or the UF rate is manually changed or set to minimum. The profile is kept in memory so that the operator can manually restart it when desired.

Specific patient profiles can be saved, recalled, and adjusted individually. If the profiled UF volume does not match the target UF volume, the profile (graph) will automatically shift up or down so that the two volumes match when the GRAPH VERIFY button is touched. The shifted graph is verified by touching the VERIFY button. If the shifted graph is not verified, it will shift back to its original position in approximately 6 seconds. The minimum and maximum UF set by the service technician in customizing always remain at the same value.

8.5.1 UF Only

The UF Only feature permits the operator to preset sequential ultrafiltration periods and rates. UF Only intervals are indicated on the UF profiling and sodium profiling graphs by a "B" (indicating bypass) in the dialysis time bar. The Instrument keeps track of the fluid lost in manual bypass (manual UF Only), but does not count elapsed treatment time in manual bypass. However the Instrument does keep track of automatic UF Only time when the UF Profile / UF Only feature is used. The treatment data contained in the UF Data Report is listed in Section 8.5.2.

In order to conserve dialysate, the dialysate flow rate automatically drops to the minimum flow programmed during Customization (see Section 17, Customizing and Configuration). After a UF Only period, the dialysate flow rate automatically returns to the previous operator-set dialysate flow rate.

The UF Only bypass intervals ("**B**s") can be set using the Profile UF screen as follows (see Figure 8-12).

1. On the Main Screen, enter the Treatment Time and Target UF.
2. Still on the Main Screen,

a. if the Instrument is in Dialyze, press the UF Removed button on the right side of the screen

b. if the Instrument is in Prime, press the Target UF button on the right side of the screen..

3. Press the Profile UF button on the right side of the screen.

4. On the Profile UF screen, press the Graph Unlock button, then select UF Only (see red circles upper right side of screen in Figure 8-12). The label on the UF Only button will change to UF Only Verify.

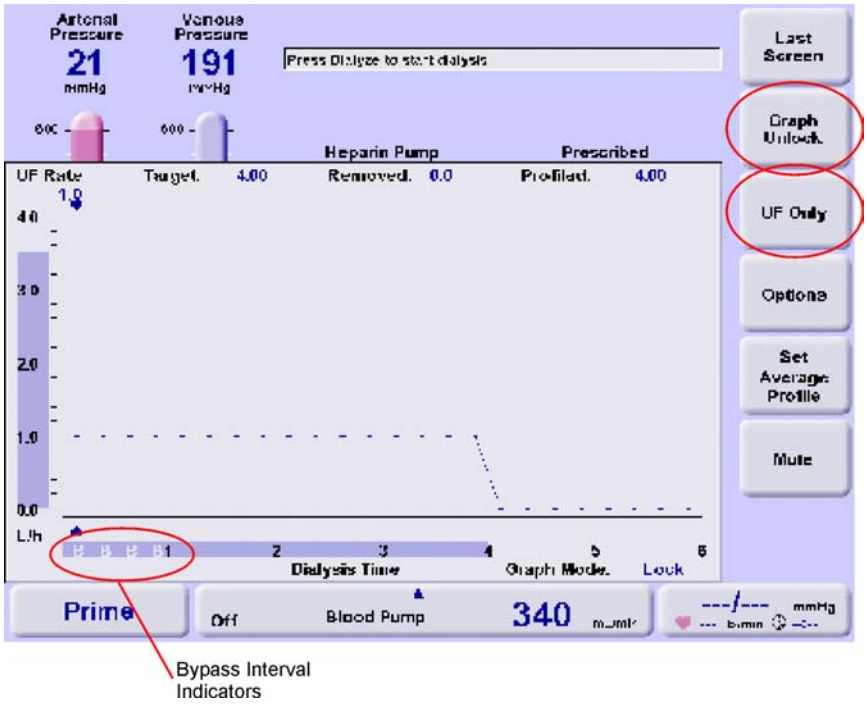

Figure 8-12. UF Only Bypass Intervals

5. Next, press the Options button, then select the UF Only interval in minutes by repeatedly pressing the UF Only Interval button. It will display "15", "30" and "60" in turn. The recommended minimum interval is 30 minutes because the intervals displayed on the graph become quite small if 15 minutes is selected.

6. Press the Last Screen button to accept the interval.

7. Program the Bypass points on the graph by touching anywhere on the graph with your finger. A "B" will appear in the intervals selected (see Figure 8-12). If touched again, the "B" is turned off. If you have difficulty turning the "B" indicators on or off, try selecting a longer interval as described in Step 5.

8. Accept the Bypass segments by pressing the UF Only Verify button.
9. Press the Graph Verify button.
10. Press the Last Screen button.
11. Press the Main Screen button.

8.5.2 UF Data Report

The following time and ultrafiltration information is displayed in the UF Data Report:

- Prescribed Treatment Time
- Elapsed Dialysis Time
- Remaining Dialysis Time
- Elapsed UF Only Time
- Remaining UF Only Time
- UF Target
- UF Removed
- UF Remaining
- UF Only Target
- UF Only Removed
- UF Only Remaining
- Calculated UF Overridden (if the operator has manually changed the calculated UF rate)

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9. DISINFECTION AND CLEANING

9.1 SPECIAL TERMINOLOGY

The following terms are important to understanding the concepts discussed in this section.

Single Pass Chemical: There is no recirculation or dwelling for this type of chemical. Recirculating or dwelling could cause damage to the Instrument. Included in this category are sodium hypochlorite and Amuchina.

Dwell Chemical: This type of chemical is recirculated and allowed to dwell (stand) in the Instrument for a certain period of time. Included in this category are Actril, Dialox, and Doxan.

Conductivity Threshold: This is the minimum conductivity value that must be reached when the disinfectant is infused into the flow path. If this value is not reached, the Instrument assumes that the wrong disinfectant is being used, and terminates the disinfect cycle. This conductivity threshold value depends on the chemical used for disinfection.

Conductivity Threshold Adjust: This is the value by which the Conductivity Threshold can be adjusted from the set value.

Prerinse Conductivity Threshold: This is the conductivity value above which the Instrument will automatically rinse the Instrument with fresh RO water until either the conductivity is equal to or less than this Prerinse Conductivity Threshold, or the Prerinse Timeout has elapsed.

Prerinse Timeout: This is the time the Instrument will be automatically prerinsed if the conductivity is above the Prerinse Conductivity Threshold when the disinfect cycle is initiated. It starts counting when the conductivity drops below 1.0 mS/cm. Prerinse will stop if the conductivity becomes equal to or less than the Prerinse Conductivity Threshold. The factory default for the Prerinse Timeout is 5 minutes.

Single Pass Chemical Alarm Trigger Time: This is the length of time after infusion begins when the Instrument will trigger an alarm if the Conductivity Threshold is not reached. The factory setting is 7 minutes @ 500 mL/min.

Dwell Chemical Alarm Trigger Time: This is the length of time after infusion begins when the Instrument will trigger an alarm if the Conductivity Threshold is not reached. The factory setting is 8 minutes @ 500 mL/min.

9.2 DISINFECTION OVERVIEW

The Arena Instrument provides alternative ways to disinfect the fluid path. Baxter recommends that the fluid path be disinfected at least once every treatment day and that regular cultures be taken of the dialysate to ensure that the bacterial level in the dialysate is acceptable. Weekly disinfection with a chemical disinfectant is recommended as a supplement to daily heat cleaning.

Available disinfection methods depend on the options included in the Instrument. They are:

- Heat
    - Heat Clean with Cool Down
    - Heat Clean with Auto Off
    - Citric Acid Heat with Cool Down
    - Citric Acid Heat Clean with Auto Off
    - Integrated Heat Clean
- Single pass chemicals: Sodium hypochlorite (1.75% and 5.25%) and Amuchina
- Dwell chemicals: Actril, Doxan, Dialox and Formaldehyde (1.06%, 2.0%, and 4.0%)

Disinfection and cleaning methods should be chosen that meet the needs of the users and provide adequate cleaning and disinfection of the Instrument.

All of the heat disinfection methods operate only in an automated mode. Each of the chemical disinfection methods may be automated or infused manually. The software offers a Disinfection Infusion Monitor feature that allows the infusion of disinfectant to be monitored.

The flow paths for single pass and dwell chemicals are shown in the diagrams at the end of this section.

Refer to the Operator's Manual for the specific disinfection procedures for this Instrument.

Caution

Proper incoming water line disinfection must be followed in order to prevent heater damage.

When a disinfection cycle is initiated, the Instrument will perform the following actions:

- Inhibit operation of the heparin pump

- Automatically set the uf rate to 3.6 l/h
- Inhibit operation of the blood pump
- Inhibit operation of the second blood pump
- Automatically time the disinfection operation
- Automatically infuse the correct amount of disinfectant chemical into the system
- Transition to a soft power off state, if selected by user
- Provide the capability to take a manual blood pressure reading, if the NIBP is installed
- Resume the disinfection where that was running prior to power loss (if power is cycled) if power is restored within 20 minutes.

9.3 HEAT DISINFECTION

9.3.1 Heat Clean

Weekly chemical disinfection is recommended as a supplement to daily heat disinfection.

NOTE

Make sure that there is an adequate air gap between the end of the drain line and the liquid level in the drain, and that the drain is vented.

Heat disinfection is an effective and accepted method of disinfection against most water-borne bacteria typically found in water supply systems and hemodialysis equipment (see Section 9.6). If bacterial contamination is from heat-resistant organisms, such as Bacillus varieties which are spore-forming bacteria, then heat disinfection may be insufficient to prevent overgrowth and formation of a biological film. In these cases of contamination, heat-cleaning may need to be supplemented with chemical disinfection on a weekly or as-required basis.

NOTE

It is the clinic's responsibility to culture frequently and identify the organisms so that the best means and schedule of disinfection may be prescribed.

The Instrument will automatically heat the water to above 85 °C and circulate the heated water through the system for a period of time set by the technician (see Section 17.3.2.2). One of two types of heat disinfection cycles may be chosen:

- Heat disinfection with automatic cool down
- Heat disinfection with automatic soft power off.

In order to start a heat disinfection cycle, the Instrument must be in the Rinse Mode and the dialyzer connectors must be on the rinse block.

- If the conductivity is above 3.2 mS/cm when the heat disinfection cycle is started, the fluid path will be rinsed until the conductivity reaches 1.0 mS/cm, then a timed rinse of 5 minutes (or until conductivity is 0 mS/cm, whichever occurs first) is performed before recirculation begins.
- If the conductivity is between 3.2 mS/cm and 0.1 mS/cm, then a timed rinse of approximately 4 minutes is automatically performed before recirculation begins.

When the Heat Disinfection Mode is initiated, the following events occur:

- The disinfection program name is displayed in the Instrument mode area (lower left).
- A data report with the disinfection program appears on the screen.
- Recirculation and rinse valves open.
- The water on/off valve is closed.
- The bypass valve toggles.
- The flow rate is set at 500 mL/min.
- The air removal pump speed is lowered by 2/3.
- The desired "dialysate" temperature is set to 85°C (97°C at the heater output).

WARNING

Manually starting Cool Down will abort the Heat Disinfection Mode. If Heat Clean is cancelled before completion, the Instrument must not be used on a patient until it is properly disinfected. This can be done by completing a Heat Clean cycle, or by performing a dwell Chemical Disinfect. Do not use single pass disinfectants because they will not completely disinfect the Instrument once any procedure with recirculation has been initiated and cancelled.

The supply pump rate is fixed after approximately 3 minutes of elapsed heat clean time.

The time required for the fluid path temperature to reach values required for disinfection (85 to 95°C) is largely dependent on the operating conditions of the Instrument when the Heat Clean cycle is initiated. The Heat Disinfection Data Report displays the heat clean steps along with their estimated remaining time and the total estimated remaining time for the cycle.

If a dialyzer connector is removed from the rinse block, the Instrument will go into bypass and the following message will appear.

"Put Dialyzer Connectors on Rinse Block!"

Once the dialyzer connectors are back on the rinse block, the following message will also appear.

"Please Take the Machine Out of Bypass!"

Pressing the dialyze bypass switch will restart the dialysate flow through the dialyzer circuit lines.

WARNING

To prevent being burned, do not open the fluid path during the Heat Clean cycle.

At the end of the recirculation period, the Instrument automatically goes into either soft power off or cool down, depending on whether "Heat Clean Auto Off" or "Cool Down" was selected by the operator.

To start a heat disinfection cycle:

1. Confirm the Instrument is in the Rinse Mode.
2. Touch RINSE MENU.
3. Touch HEAT CLEAN MENU.
4. Select either Heat Clean or Heat Clean Auto Off.
5. Touch VERIFY.

The message "!Warning! Heat Clean in Process" will be displayed and the Heat Clean Cycle will be initiated. Make sure the dialyzer and concentrate lines become hot to the touch.

The date of the last completed heat clean and the last completed automated chemical disinfection is displayed in the disinfect data report when the **RINSE MENUS** button is touched. An error message for a failed disinfect cycle is displayed in the Heat Clean Data Report upon power on following the cycle.

The fluid path temperature is monitored during the recirculation period. The message "Unstable Heat Clean Temp!" flashes in the instruction window if the fluid path temperature drops below 85°C but remains above 80°C for a limited time during the heat clean recirculation period. The message "Disinfection Not Complete!" flashes in the instruction window if the temperature drops below 80°C or if the temperature remains between 80 and 85°C longer than approximately 10 minutes during the heat clean recirculation period.

9.3.2 Automatic Cool Down

When the heat clean time is complete, the Instrument enters the Cool Down Mode unless Auto Off was selected. The Cool Down Mode "dialysate" flow rate is set at 800 mL/min or the Instrument-calibrated maximum flow rate (if lower) until the primary high temperature alarm has ceased. When the primary temperature is out of alarm, the Instrument will revert back to the Rinse Mode.

This Cool Down Mode requires 6 to 8 minutes at a flow rate of 800 mL/min.

9.3.3 Auto Off (Automatic Soft Power Off)

When the Heat Clean time is complete, the Instrument enters Soft Power Off Mode. Cool down is not used. The fan will remain on until the primary temperature is out of alarm limits.

9.3.4 Heat Clean with Citric Acid

Citric Acid may be infused into the flowpath during Heat Clean to enhance the disinfection and as a cleaner for bicarbonate precipitate. See Section 17.3.5 for initial setup of Citric Acid Heat Clean parameters. Additional hardware is required for automated Citric Acid Heat Clean (see Section 2.4.4). The automated Citric Acid Heat Clean option is not available in all markets.

9.3.4.1 Citric Acid Solution Preparation and Infusion

WARNING

Be careful when handling citric acid solutions. Read and follow the instructions for the safe handling of citric acid on the warning label on the citric acid bottle and follow your center's guidelines for use.

The concentration of a solution is sometimes described as a percentage in grams of a solute ion in a liter of solution. It may also be described as the number of grams of the solute per liter of solution (g/L).

A 10% solution will contain 100 grams of citric acid per one liter of solution (100 g/L). This solution may be prepared easily using food-grade citric acid (anhydrous) by dissolving the citric acid in purified water. For example, in order to prepare one liter of 20% citric acid solution, 200 grams of citric acid powder would be dissolved in purified water to produce a total volume of one liter.

Do not directly add the citric acid to one liter of water, otherwise the resulting citric acid concentration will be less than expected because the final volume will be greater than one liter.

The volume of citric acid to be infused into the Instrument, depends on the desired concentration in the fluid path. Table 9-1 summarizes the infusion volumes (milliliters) expected for different concentrations of citric acid. The infusion rate of the acid pump is approximately 40 mL/min.

To calculate the infusion time, divide the infusion volume by 40 mL/min (the acid pump speed). The result will be the infusion

time in minutes. The infusion time varies from 16.5 seconds to infuse 11 mL of 500 g/L citric acid to 4 minutes and 7 seconds to infuse 165 mL of 100 g/L citric acid.

Table 9-1. Citric Acid Volume to Be Infused

		Final Dialysate Concentration (g/L)				
		2.0	3.0	4.0	5.0	6.0
Citric Acid (g/L)	100	55	82	110	137	165
	150	35	55	70	92	110
	200	27	41	55	69	82
	250	22	33	44	55	66
	300	17	27	35	46	55
	350	15	24	31	42	48
	400	14	21	27	39	41
	450	12	19	25	33	37
	500	11	17	22	27	33

Table Note: *Values inside the darker box are in milliliters (mL).*

Example:

Using Table 9-1, when citric acid at a concentration of 250 g/L is infused to achieve a fluid path (final dialysate) of 6.0 g/L, a volume of 66 mL must be infused for 1 minute and 39 seconds (see equation below).

$$\frac{66\ \text{mL}}{40\ \text{mL/min}} = 1.65\ \text{minutes} = 1\ \text{minute}\ 39\ \text{seconds}$$

The desired citric acid concentration is monitored by the Instrument during automatic infusion by means of the citric acid's conductivity value.

The expected conductivity vs. citric acid concentration is shown in Table 9-2. Along with the expected conductivities are detection thresholds that *must* be met in order for the Citric Acid Heat Disinfection cycle to function properly. The detection threshold may be set closer to the expected conductivity value (see Section 17.3.5.8).

Table 9-2. Conductivity Thresholds

Citric Acid Concentration (g/L)	Expected Conductivity (mS/cm)	Detection Threshold (mS/cm)
2.0	0.9	0.6
3.0	1.2	0.9
4.0	1.4	1.1
5.0	1.6	1.3
6.0	1.8	1.5

9.3.4.2 Automatic Infusion

The date of the last completed Heat Clean and the last completed automated chemical disinfection is displayed in the Last Disinfection Data Report when the RINSE MENU button is touched.

Preconditions

- The patient is disconnected from the dialyzer and blood lines.
- The dialyzer connectors are connected to the rinse block.

Procedure

1. Make sure there is citric acid in the citric acid container on the back of the Instrument.
2. Touch RINSE MENU.
3. Touch HEAT CLEAN MENU, CITRIC ACID HEAT CLEAN, then VERIFY.
4. Allow Citric Acid Heat Clean and Cool Down to complete.
5. After the Instrument returns to the Rinse Mode, allow it to rinse for 15 minutes.
6. Obtain a sample of the rinse solution from the dialysate line sample port and check for residual citric acid using a test specific for citric acid.
   a. If the residual citric acid content is within acceptable limits, the machine can be prepared for dialysis.
   b. If the machine is not within acceptable limits, continue to rinse the machine until the level is acceptable.

9.3.4.3 Manual Infusion

Preconditions

- The patient is disconnected from the dialyzer and blood lines.
- The dialyzer connectors are connected to the rinse block.
- The machine is in Rinse Mode and has been rinsed with water for at least 10 minutes.
- The conductivity is less than 1 mS/cm.
- The dialysate flow rate is 500 mL/min.

Procedure

1. Touch RINSE MENU.
2. Touch HEAT CLEAN MENU, HEAT CLEAN, then VERIFY.
3. Connect the acid/acetate concentrate line (pink connector) to a container of citric acid solution. The acid concentrate line is used to infuse a fixed volume of citric acid (refer to Table 9-1 to determine the quantity of citric to be infused).
4. Infuse the desired citric acid solution into the fluid path.
5. Disconnect the acid/acetate concentrate line from the disinfect container and connect it to the acid/acetate rinse port (pink).
6. Allow Heat Clean and Cool Down to complete.
7. After the Instrument returns to the Rinse Mode, allow to rinse for 15 minutes.
8. Obtain a sample of the rinse solution from the dialysate line sample port and check for residual citric acid.
   a. Check for residual citric acid content with a test specific for citric acid.
   b. If the residual citric acid content is within acceptable limits, the Instrument can be prepared for dialysis. If the Instrument is not within acceptable limits continue to rinse until the level is acceptable.

WARNINGS

Make sure that the determination test shows a sufficiently low level of citric acid in the rinse solution before dialysis. Refer to the attending physician's directives for the acceptable limit and the AAMI standard for hemodialysis.

To ensure that the citric acid level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse solution in the dialysate lines.

Make sure that the determination test is specific for the chemical used.

NOTE

An error message will appear on the screen accompanied by an audio "beep" while the acid connector is removed from the machine. This error message states, "Put concentrate connectors on block". Mute this error while infusing citric acid.

When the citric acid has been infused, replace the acid connector on the machine.

9.3.5 Integrated Heat Clean

The Integrated Heat Clean Disinfection is a future option that will permit the operator to preset the Instrument to automatically start an Integrated Heat Clean disinfection cycle at a preset time and infuse hot water from a heated water treatment system, thus heat-disinfecting the Instrument's incoming water line, fluid path, and drain line.

This option will require hardware changes of the following elements capable of withstanding the heat:

- Inlet water line
- Drain line
- Inlet water pressure regulator.

See Sections 17.3.5.1, 17.3.5.2, and 17.3.5.5 for customizing information.

9.4 CHEMICAL DISINFECTION

WARNING

Do not use any kind of non-approved disinfectant.

Chemicals may be infused into the flowpath for disinfection, enhancement of disinfection, and cleaning. Some chemicals are both cleaners and disinfectants. Baxter recommends the use only of disinfectants and cleaning agents that are specifically mentioned in the pertinent sections of this manual and assumes no responsibility for equipment damage or inadequate disinfection resulting from the use of other products.

Table 9-3. Disinfectants and Cleaning Agents

Disinfectant / cleaning agent	Use
Actril	Peracetic acid based disinfectant
Citric acid	Enhanced heat disinfection. Also used as a cleaner for bicarbonate precipitation.
Dialox	Peracetic acid based disinfectant
Doxan	Peracetic acid based disinfectant
Formaldehyde	Disinfectant
Sodium hypochlorite (bleach)	Effective disinfectant at 500 ppm. Also used as cleaner for biological deposits.
Vinegar	Only used as a cleaner for bicarbonate precipitation.

9.4.1 Single Pass Chemicals

Single Pass Chemicals do not require recirculation and dwell time in the fluid pathway for disinfection or cleaning. Recirculation or dwelling of these chemicals may cause damage to the Instrument. Single Pass chemicals approved for use as disinfectants in the Instrument flowpath are sodium hypochlorite (1.75% and 5.25%) and Amuchina.

9.4.1.1 Chlorine-based Disinfectants

The most common disinfectant is household bleach, which is sodium hypochlorite. It is corrosive and must be rinsed from the system within a short period. When rinsing is done at the end of the patient treatment, the rinse water could contain some bacteria. This may resume growth and overnight contamination can be significant. AAMI recommends using chlorine just before using the dialysis machine for a patient treatment (AAMI, 1990, pp. 81-94).

During dialysis flow, bacteria usually do not colonize or adhere to surfaces. Therefore, if the dialysis machine is kept running, it may be unnecessary to disinfect between dialysis treatments (Bland & Favero, 1990).

The highest sodium hypochlorite concentration for which the Instrument is designed is 5.25%. If 6% is used, it will be necessary to dilute it with RO water.

CAUTION

Using 6% bleach may accelerate damage to internal fluid path components.

How to make 5.25% bleach from 6%

- To a 96-ounce container of Clorox Ultra, add 14 ounces of RO water.
- To a 180-ounce container of Clorox Ultra, add 27 ounces of RO water.
- If you are using a 1000 mL disinfect bottles, use 875 mL of 6% bleach and 125 mL of RO water.

  The formula to calculate the amount of water to be added to achieve the proper dilution is:

  Volume of 6% bleach X 0.143 = Amount of RO water needed.

  Example: 875 mL of 6% bleach X 0.143 = 125 mL of RO water.

CAUTION

The Clorox Company has another product called Clorox Advantage that is packaged in a container with a similar label. This product contains a fair amount of added sodium hydroxide. The combination sodium hypochlorite (bleach) and sodium hydroxide (caustic soda) is definitely NOT something that should be used in a Baxter Instrument!

Do not use Clorox Advantage in any Baxter hemodialysis Instrument. Damage will occur to internal fluid path components.

9.4.1.2 Amuchina

Amuchina is described as an electrolyte chloreoxidizer. It is a sodium hypochlorite solution which is manufactured by the partial electrolysis of sodium chloride. Amuchina is 18% sodium chloride and claims that tests have shown it to be nontoxic to skin

and mucous membranes. The pH is approximately 9.5, which makes Amuchina less alkaline than bleach. When Amuchina breaks down, the result is sodium chloride and water.

Amuchina is stable for several years when kept in its original container, and has good penetrating power due to the presence of hypochlorous acid (HClO).

9.4.2 Dwell Chemicals

Dwell Chemicals require an extended exposure time in the flowpath for disinfection. These chemicals are recirculated and allowed to remain in the Instrument for a certain period of time. Dwell chemicals approved for use in the flowpath are Actril, Doxan, Dialox and formaldehyde. Only approved chemicals should be used in the flowpath.

9.4.2.1 Actril, Dialox, and Doxan

Actril, Dialox and Doxan contain hydrogen peroxide, peracetic acid, and acetic acid in different proportions. See Table 9-4.

Table 9-4. Actril, Dialox and Doxan Postdilution Composition

Component	Actril	Dialox	Doxan
Hydrogen peroxide	1.00%	6.0 - 8.0%	<20%
Peracetic acid	0.08%	0.1- 1.0%	≈1%
Acetic acid	5.20%	2.0 - 10.0%	<10%

Prolonged dwelling may cause deterioration of the Instrument's components. They are good *combination* disinfectants and decalcification chemicals which decompose into oxygen, water, and acetate which is easily metabolized in nature.

These chemicals oxidize the walls and components of the microbial cell resulting in the neutralization and destruction of micro-organisms with no possibility of adaptation or acquiring resistance.

The presence of acetic and peracetic acids gives them their descaling properties. A dialysis Instrument that is disinfected daily with these chemicals should not require additional treatment with an acidic descaling product such as vinegar.

Actril is not just diluted Renalin. Table 9-5 compares these two chemicals. The key point here is that there is a very different **ratio** of hydrogen peroxide to peracetic acid.

Table 9-5. Ratio of Hydrogen Peroxide to Peracetic Acid

Chemical	% of Chemicals Dissolved in Water*	Ratio of Hydrogen Peroxide to Peracetic Acid
Actril	1.00% hydrogen peroxide 0.08% peracetic acid	12.5:1
Renalin	20% hydrogen peroxide 4% peracetic acid	5:1

**Information from the Material Safety Data Sheet (MSDS)*

NOTE

Baxter has not tested the disinfection effectiveness of Renalin in the Arena Instrument. The use of Renalin can accelerate damage to the fluid path components.

9.4.2.2 Formaldehyde

Formalin is a solution containing 37% to 55% by weight of formaldehyde gas in water with 10 to 15% methanol added to prevent polymerization. It is only as corrosive as water. It can penetrate into most areas where bacteria grow (AAMI, 1990, pp. 81-94). Current Intelligence Bulletin 34 (U. S. Department of Health and Human Services, National Institute for Occupational Safety and Health, April 1981) cited formaldehyde as a possible carcinogen source and specifying controls used to limit worker exposure. Formaldehyde should not be left inside the Instrument for more than 30 days or crystalization may occur.

9.4.3 Automated Chemical Disinfection

The Instrument provides the operator with Instrument dilution ratio, timed infusion, recirculation and dwell (if applicable), and forced rinse appropriate for the disinfecting chemical. The type(s) of chemical disinfectants can be selected by the service technician (see Section 17.3.2).

To access the fluid path disinfection controls, touch the RINSE MENU button. The date, time, method, and type of disinfection of the last complete automated fluid path disinfection (heat and chemical) are displayed in the Last Disinfection Data Report. To access the chemical disinfection controls, touch the CHEMICAL MENU button.

9.4.3.1 Amuchina and Sodium Hypochlorite

CAUTION

Do not allow sodium hypochlorite or Amuchina to remain in the fluid path longer than the recommended time or damage to the Instrument may result.

Touch the SODIUM HYPO and VERIFY buttons. The Instrument prompts the operator to make the necessary concentrate line connections. If the conductivity is above 0.1 mS/cm, the Instrument will automatically prerinse the fluid path before disinfectant infusion.

The "dialysate" flow rate during sodium hypochlorite infusion is the rinse flow rate before the Chemical Mode started.

After the required chemical infusion, the Instrument prompts the operator to make the necessary concentrate line connections, then rinses the Instrument at a flow rate set by the technician.

When the timed forced rinse is completed, the Instrument prompts the operator to test for residual disinfectant.

When the residual disinfectant level is within the acceptable range and the YES button touched, the Instrument automatically returns to the Rinse Mode.

If the cycle is fully completed without interruption, the date and time of last disinfection will be displayed in the chemical screen message window.

In the event of a power failure of approximately 20 minutes or less, the Instrument returns to the state it was in before the power failure. If a power failure longer than 20 minutes occurs, the Instrument will go to the forced rinse state and prompt the operator to make the necessary concentrate line connections.

9.4.3.2 Actril, Dialox, Doxan, and Formaldehyde

Touch the Disinfectant button (as selected per Section 17.3.2.5) and VERIFY buttons. The Instrument prompts the operator to make the necessary concentrate line connections. If the conductivity is above 0.1 mS/cm, the Instrument will automatically prerinse the fluid path before disinfectant infusion.

The "dialysate" flow rate during Actril infusion is automatically set to 500 mL/min.

After the required chemical infusion, the Instrument prompts the operator to make the necessary concentrate line connections and the solution is recirculated for the appropriate time.

The Instrument then automatically powers off for a dwell time.

- If the Instrument is powered up before the dwell time of approximately 30 minutes (10 minutes for Dialox, 2 hours for Formaldehyde) is complete, the Instrument will prompt the operator about the incomplete dwell time then automatically shut off.
- If the operator needs to use the Instrument, the operator may start forced rinse and interrupt the chemical cycle.

After the required dwell, the Instrument prompts the operator to make the necessary concentrate line connections, then rinses the Instrument at a technician-set flow rate. (See 17.3.2.3.)

When the timed forced rinse is completed, the Instrument prompts the operator to test for residual disinfectant.

When the residual disinfectant level is within the acceptable range and the YES button touched, the Instrument automatically returns to the Rinse Mode.

If the cycle is fully completed without interruption, the date and time of last disinfection will be displayed in the chemical screen message window.

In the event of a power failure the Instrument returns to the state it was in before the power failure provided the power failure does not last longer than 20 minutes.

9.4.4 Forced Rinse

The forced rinse time in minutes is dependent upon the disinfectant, the technician-set forced rinse flow rate, and the technician-set sampling location. (See Section 17, Customizing and Configuration). These relationships are shown in Tables 9-6 and 9-7.

Table 9-6. Forced Rinse Time in Minutes for Sampling at the Drain Line

Flow Rate	Dialox	Doxan	Amuchina & Sodium Hypochlorite	Actril	Formaldehyde		
					1.06%	2%	4%
300	72	83	27	52	29	39	46
400	54	62	25	39	27	37	43
500	43	50	23	31	25	35	40
600	36	42	21	26	23	33	37
700	31	36	19	22	21	31	34
800	27	31	17	20	19	29	31
900	24	28	15	17	17	27	28
1000	22	25	13	16	15	25	25

Table 9-7. Forced rinse time in minutes for sampling location: Sample Port

Flow Rate	Dialox	Doxan	Amuchina & Sodium Hypochlorite	Actril	Formaldehyde		
					1.06%	2%	4%
300	67	67	12	44	24	29	36
400	50	50	11	33	22	27	33
500	40	40	10	26	20	25	30
600	33	33	9	22	18	23	27
700	28	28	8	19	16	21	24
800	25	25	7	17	14	19	21
900	22	22	6	15	12	17	18
1000	20	20	5	13	10	15	15

9.4.5 Disinfect Incoming Water Line

It is suggested that the incoming water line be disinfected at Instrument installation and then as required (or at least every three months). Baxter recommends that regular cultures be taken of the dialysate to ensure that the bacterial level in the dialysate is acceptable. See Section 9.10.1.2.

WARNING

For Instruments with On-Line Hemodiafiltration and or dialysate filters, the filters must be removed and bypassed with shunt fittings prior to this procedure.

9.4.5.1 Supplies Needed

- Gloves resistant to the disinfectant
- Diluted sodium hypochlorite solution: 150 mL 5.25% household sodium hypochlorite mixed with 4500 mL (4.5 L) cold water

9.4.5.2 Preconditions

- The patient is disconnected from the dialyzer and blood lines.
- The dialyzer connectors are connected to the rinse block.
- The Instrument is in rinse and has been rinsed with water for at least 10 minutes prior to infusing a disinfectant.

9.4.5.3 Procedure

1. Set the dialysate flow rate to 300 mL/min.
2. Soft power off the Instrument.

3. Place the container of prediluted sodium hypochlorite on the floor near the water supply valve.
4. Turn off the water supply.
5. Disconnect the incoming water line from the water supply valve.
6. Place the free end of the incoming water line in the container of prediluted sodium hypochlorite.
7. Raise the container of prediluted sodium hypochlorite above the height of the top of the hydraulics compartment.
8. Turn on the Instrument and start the Rinse Mode.
9. Infuse the prediluted sodium hypochlorite for approximately 15 minutes.
10. After the 15-minute infusion, make sure that most of the sodium hypochlorite solution (approximately 4.5 L) has been infused.

    If the solution was not infused, prime the incoming water line with water and infuse the sodium hypochlorite solution by repeating Steps 6, 7 and 9.
11. Connect the incoming water line to the water supply valve.
12. Rinse the Instrument until it is free of sodium hypochlorite.
13. After 15 minutes, obtain a sample of the rinse solution and check for residual sodium hypochlorite using a test specific for sodium hypochlorite.
    a. If the residual sodium hypochlorite content is within acceptable limits, the Instrument can be prepared for dialysis.
    b. If the residual sodium hypochlorite content is not within acceptable limits, continue to rinse the Instrument until the level is acceptable.

WARNING

Make sure that the determination test shows a sufficiently low level of disinfectant in the rinse solution before dialysis. Refer to the attending physician's directives for the acceptable limit and the AAMI standard for hemodialysis.

To ensure that the disinfectant level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse solution in the dialysate lines.

9.5 DISINFECT INFUSION MONITOR

The Disinfect Infusion Monitor (DIM) is designed to verify that the desired level of chemical disinfectant is infused into the fluid path and to alert the operator if infused disinfectant is not detected.

The DIM determines the presence of the disinfectant by measuring the conductivity of the solution. Because formaldehyde is not conductive, formaldehyde cannot be monitored by the DIM.

It also monitors the conductivity when a chemical disinfect cycle is started to make sure there are no other chemicals in the flow path. The Instrument will automatically start a prerinse cycle and continue rinsing the Instrument with fresh RO water until the conductivity is less than or equal to the Prerinse Conductivity Threshold or the Prerinse Timeout has elapsed.

A qualified service technician can customize the Instrument to enable or disable the DIM. It can also be customized for one single pass disinfectant and one dwell disinfectant. Refer to Section 17.3.2. for the DIM settings.

WARNING

Using sodium hypochlorite or Amuchina in Instruments with On-Line Hemodiafiltration or dialysate filters will damage the filters.

Note that single pass chemicals are not allowed on an Instrument equipped with OLHDF or Dialysate Filters.

9.5.1 Prerinse for Chemical Disinfect

When chemical disinfectant is started, the Instrument rinses with fresh water until the conductivity reaches 1.0 mS/cm displaying "Chem Disinfect: Pre-Rinse" in the instruction window. After the conductivity has reached 1.0 mS/cm, the Instrument continues to rinse until the conductivity reaches the prerinse conductivity threshold (by default 0.0 mS/cm) or the prerinse timeout (5 minutes).

If the conductivity of the rinse water is greater than zero, the Disinfect Infusion Monitor can be disabled (see Section 17.3.2.8), or the prerinse conductivity threshold can be raised to 0.1 or 0.2 mS/cm, but only by changing a calibration constant (see Section 5.4.7). The Instrument calculates the difference between the conductivity reading at the time of the disinfectant infusion and the conductivity reading when the Instrument last transitioned from prerinse to infusion. If it is greater than or equal to the

conductivity threshold value, then the Instrument assumes that the correct chemical was properly infused.

If the DIM is not enabled or the disinfection chemical is formaldehyde, the Instrument will be rinsed with fresh water for 2 minutes if the conductivity was greater than 1 mS/cm at the start of prerinse.

When a prerinse cycle is initiated the Instrument will perform the following actions.

- It displays the message “Put Dialyzer Connectors on Rinse Block” in the instruction window if either sensor for the dialysate connectors does not detect the presence of a connector.
- It displays the message “Chem Disinfect: Pre-Rinse” in the instruction window when the concentrate and dialysate connectors are on the rinse block.
- It sets the “A” concentrate pump rate to the 35:1 proportioning ratio rate.
- It sets the “B” concentrate pump rate to the 20.13:1 proportioning ratio rate.
- It opens the rinse valve (dialysate pressure relief valve).
- It cycles the bypass valve into bypass for 5 seconds every minute.
- It cycle the dialysate filter purge valve #2 if Dialysate Filter hardware is installed (refer to Section 24).
- It enables the level control of the incoming water valve.
- It de-energizes the recirculation valve.
- It holds the elapsed time counter when any of the following conditions occur:
    - No Incoming Water alarm.
    - Flow Restricted alarm.
    - No Dialysate Flow alarm.
    - Concentrate connectors are not on the rinse block.
    - Dialysate connectors are not on the rinse block.

9.5.2 Chemical Infusion

Chemical infusion can start after completion of a forced rinse or if the conductivity is equal or less than the prerinse conductivity threshold. The Instrument infuses the disinfectants according to the parameters shown in Table 9-8. During infusion "Chem Disinfect: Infusion" will be displayed in the instruction window.

Table 9-8. Disinfectant Infusion Parameters

Disinfectant Name	Disinfec. Type	Infusion Ratio "A" Pump	Alarm Trigger Time (min)	Conductivity Threshold (mS/cm)	Infusion Time @ 500 mL/min	Recirc. Time (min)	Dwell Time
Actril	Dwell	9:1	8	0.7	8 min	5	30 min
Amuchina	Single Pass	34:1	7	7	15 min	N/A	N/A
Dialox	Dwell	34:1	8	0.4	8 min	5	10 min
Doxan	Dwell	9:1	8	0.4	8 min	5	30 min
Formaldehyde 1.06%	Dwell	34:1	8	N/A	8 min	5	2 hours
Formaldehyde 2%	Dwell	35:1.89	8	N/A	8 min	5	2 hours
Formaldehyde 4%	Dwell	35:3.77	8	N/A	8 min	5	2 hours
Sodium Hypochlorite 1.75%	Single Pass	34:1	7	1.6	15 min	N/A	N/A
Sodium Hypochlorite 5.25%	Single Pass	34:1	7	4.8	15 min	N/A	N/A

After the infusion time given in Table 9-8, the conductivity is measured. The single pass chemical infusion alarm trigger change time can be adjusted to between 2 and 15 minutes but only by changing a calibration constant (see Section 5.4.7). If the conductivity has not increased above the level measured at the start of infusion by an amount equal to the conductivity threshold, disinfection fails and the Instrument creates an alarm to notify the operator that the disinfection cycle was not completed. The operator is alerted with the message "Infusion Failed – Check Disinfectant". The operator can correct the problem and press "Restart Infusion" or start Forced Rinse.

If a dwell disinfectant is in use, the Instrument will soft power off for the prescribed time, after infusing of the disinfectant.

When an infusion cycle is initiated the Instrument will perform the following actions:

- It displays the message “Put Dialyzer Connectors on Rinse Block” in the instruction window, if either sensor for the dialysate connectors do not detect the presence of a connector.
- It displays the message “Chem Disinfect: Infusion” in the instruction window when the concentrate and dialysate connectors are on the rinse block.
- It sets the “A” concentrate pump rate according to Table 9-8.
- It sets the “B” concentrate pump rate to the 20.13:1 proportioning ratio rate.
- It cycles the bypass valve into bypass for 5 seconds every minute.
- It opens the dialysate filter purge valve #2 if Dialysate Filter hardware is installed (refer to Section 24).
- It enables the level control of the incoming water valve.
- It de-energizes the recirculation valve.
- It holds the elapsed time counter when any of the following conditions occur:
    - No Incoming Water alarm.
    - Flow Restricted alarm.
    - No Dialysate Flow alarm.
    - Concentrate connectors are not on the rinse block.
    - Dialysate connectors are not on the rinse block.

9.5.3 Recirculation

When a recirculation cycle is initiated, the Instrument will perform the following actions.

- It ensures the concentrate connectors are connected to their assigned ports.
- It displays the message “Chem Disinfect: Recirculation” in the instruction window when the concentrate and dialysate connectors are on the rinse block.
- It sets the “A” concentrate pump rate to the 35:1 proportioning ratio rate.
- It sets the “B” concentrate pump rate to thte 20.13:1 proportioning ratio rate.
- It opens the rinse valve (dialysate pressure relief valve).

- It cycles the bypass valve into bypass for 5 seconds every minute.
- It cycles dialysate filter purge valve #2 if Dialysate Filter hardware is installed (refer to Section 24).
- It disables the level control of the incoming water valve.
- It energizes the recirculation valve.

9.5.4 Forced Rinse

After infusion of single pass disinfectants or after the dwell time for dwell disinfectants, the Instrument enters a Forced Rinse. The rinse time will be as specified in Table 9-6 or Table 9-7. The forced rinse time may be extended. See Section 17, Customizing and Configuration, for details. Perform a test to determine that the disinfectant is rinsed. If the flow path is free of chemical disinfectant, the Forced Rinse can be ended and the Instrument returned to Rinse Mode.

WARNING

Make sure that the determination test shows a sufficiently low level of disinfectant in the rinse solution before dialysis. Refer to the attending physician's directives for the acceptable limit and the AAMI standard for hemodialysis.

To ensure that the disinfectant level in the dialyzer circuit is below a level acceptable for patient safety, sample the rinse solution in the dialysate lines.

Make sure that the determination test is specific for the disinfectant used.

9.5.5 Troubleshooting Chemical Infusion Problems

If the chemical disinfection fails because the conductivity threshold is not reached, perform the following.

1. Verify that the chemical being used to disinfect contains the correct amount of active ingredient.
2. Use a reference meter to monitor the temperature and conductivity during chemical infusion. Calibrate the temperature and conductivity as required.

3. Verify the "A" Concentrate Pump and Dialysate flows. Calibrate the "A" Concentrate Pump, "B" Concentrate Pump and Dialysate flows as required.
4. Verify the connection of the disinfect infusion line to the disinfectant.
5. Verify that the flow path between the disinfectant container and the "A" Concentrate Pump does not have leaks.
6. Observe the disinfectant infusion cycle.
   a. If the infusion fails, immediately restart the infusion.
   b. If the infusion passes on the second attempt, then the Single Pass Chemical Alarm Trigger Time may have to be adjusted (applicable only for Single Pass disinfectants), but this can be done only by changing a calibration constant (see Section 5.4.7). Call Baxter Instrument Services if any Calibration Constant must be changed.
   c. If the threshold still cannot be reached, you may have to adjust the conductivity threshold, but this can be done only by changing another calibration constant (see Section 5.4.7). Call Baxter Instrument Services if any Calibration Constant must be changed.

It is the clinic's responsibility to verify and monitor the successful disinfection of the Instrument.

9.6 FLOWPATH CLEANING

9.6.1 Rinse Fluid Path with Vinegar

If the type of chemical infused through the disinfect line is changed, rinse the disinfect line with water for approximately 2 minutes before connecting the line to the chemical container.

9.6.1.1 Overview

The goal of this procedure is to remove bicarbonate precipitate (insoluble calcium carbonate deposits) from the Instrument fluid path. Bicarbonate precipitate is a white to cream-colored deposit formed downstream of the bicarbonate mix point. Other precipitates and/or discolorations will not be removed by following this procedure.

Although the Instrument does not inherently cause bicarbonate precipitate, environmental conditions may cause precipitate buildup.

It is important to follow this vinegar rinse procedure if bicarbonate precipitate is present in the flow path. If allowed to accumulate excessively, bicarbonate precipitate can cause problems with the operation of the Instrument. It is recommended that this procedure be done at least once a week if the clinic is not using Dialox, Doxan, or Actril.

This procedure will not prevent bicarbonate precipitate formation. It is useful only in controlling accumulation of the deposit. Perform this procedure as often as conditions indicate. If precipitation is significant, this procedure may have to be repeated multiple times.

9.6.1.2 Supplies Needed

- White vinegar (5% acetic acid solution)
- pH color indicator strips, range pH 6 to 8

9.6.1.3 Precondition

- Patient disconnected.
- Instrument is in Rinse Mode, rinsing with water.
- Dialysate flow rate is 800 mL/min.

9.6.1.4 Procedure

1. Check the pH of the rinse water using a pH indicator strip. This will establish a baseline pH value to which the system should be rinsed after exposure to the vinegar.
2. Connect the disinfect line to the container of vinegar.
3. Connect the acid/acetate concentrate line to the disinfect port.
4. Infuse approximately 800 mL of vinegar into the fluid path. This will take approximately 30 minutes.
5. Before the vinegar supply is completely exhausted, turn off the Instrument.
6. Allow the vinegar to remain in the fluid path for approximately 30 minutes. For high precipitate build-up allow 60 minutes.
7. Meanwhile, remove the acid/acetate concentrate line from the disinfect port and put it back on the “A” rinse port.
8. Remove the disinfect line from the vinegar supply and connect the line to the disinfect rinse fitting.
9. After the dwell time, turn on the Instrument and start rinse.
10. Set the dialysate flow rate to 800 mL/min.
11. Rinse the fluid path for at least 15 minutes.

12. Inspect the dialysate lines.
    a. If precipitate is still present, an infusion of another fresh supply of vinegar is required; repeat Steps 2 through 10.
    b. If the lines are clean, go to the next step.
13. Using pH indicator strips, check the pH of the rinse water.
14. Continue rinsing as required until the pH of the rinse water has returned to the value noted in Step 1, above.

9.6.2 Biological Deposits in the Drain Line

9.6.2.1 Overview

The Heat Clean Mode without Auto Off is an excellent method for disinfecting the Instrument fluid path as well as to break down biological deposits.

Weekly disinfection with diluted bleach is also recommended for the Instrument to disinfect the drain line.

Due to a number of reasons, biological material may build up in the drain line. Some possible reasons are:

- Lack of adequate rinse before disinfection.
- Drain line pushed too deeply into the drain. There should be an air gap between the drain line and the water in the drain.
- Inadequate chemical disinfection.

Biological material in the drain line may cause the following problems:

- Failure of the TMP in Self Test.
- Unable to start Self Test because TMP is in “negative TMP alarm” during the Rinse Mode.
- Flow Restricted alarms.

9.6.2.2 Supplies Needed

- 1 liter 5.25% sodium hypochlorite (household bleach)

9.6.2.3 Precondition

- Patient is disconnected.
- Instrument has been rinsed for at least 10 minutes with water.
- Instrument is in Rinse Mode.

9.6.2.4 Procedure

1. Make sure that there is an adequate air gap between the drain line and the drain.

   If the type of chemical disinfectant is changed, rinse the disinfect line with water for approximately 2 minutes before connecting the line to the container of disinfectant.

2. Connect the disinfect line (yellow connector) to a container of 1 liter of household bleach.
3. Connect the acid/acetate concentrate line (pink connector) to the disinfect port (yellow).
4. Allow bleach to infuse into the fluid path.
5. After the 60 minutes, visually check the drain line for deposits.
   - If the drain line is clean, disconnect the Instrument from the bleach supply.
   - If the drain line is not clean, continue to infuse bleach until the line is clean (add more bleach to the container as needed).
6. To disconnect the Instrument:
   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).
   b. Wait approximately 15 seconds for the disinfect line to drain, then connect the disinfect line (yellow connector) to the disinfect port (yellow).

CAUTION

Do not allow sodium hypochlorite to remain in the fluid path longer than the recommended time or damage may result.

7. Rinse the Instrument for approximately 30 minutes. Continue rinsing until a test specific for the presence of sodium hypochlorite is negative.
8. Repeat the procedure as needed to remove protein buildup from the drain line.
9. Make sure that there is an adequate air gap between the drain line and the drain.

9.7 CLEAN / DISINFECT EXTERNAL SURFACES

It is recommended that this procedure be performed at least once each day.

CAUTION

Do not use other disinfecting agents or allow diluted sodium hypochlorite to dry on the external surfaces or damage may result.

The use of other disinfecting agents, including undiluted or underdiluted sodium hypochlorite may cause damage or deterioration to some Instrument surfaces, such as the touch screen.

Clean the touch screen only with 4 parts of 5.25% solution of sodium hypochlorite in 126 parts of water. The use of other chemicals may cause the screen to become clouded. Rinse it with a damp cloth.

Do not use alcohol or other solvent-based cleaners.

9.7.1 Supplies

- Mild detergent solution, such as a mild dishwashing liquid in water
- Diluted sodium hypochlorite solution (4 part 5.25% sodium hypochlorite and 126 parts cold water), for example, 40 mL 5.25% sodium hypochlorite and 1260 mL cold water
- Gloves resistant to the disinfectant

9.7.2 Procedure

1. Wipe off surface soil as required with a mild detergent solution.
2. Remove the blood pump head (rotor) and wipe it with a cloth.
3. Remove the heparin pump slide.
4. Wipe all external surfaces with diluted sodium hypochlorite solution. The blood pump head and heparin pump slide can be submerged in this solution.
5. Wipe all external surfaces with plain water. Thoroughly rinse the blood pump head and heparin pump slide.
6. Reattach the blood pump head (see Section 28.3.1).

7. Reattach the heparin pump slide (see Section 28.3.4).
8. Disinfect bicarbonate containers and dip tubes (if they are used) per clinic procedures.

9.8 BACTERIA, STERILIZATION, AND DISINFECTION

9.8.1 Definitions

9.8.1.1 Bacterium

A bacterium is a member of a class of microscopic organisms having a round, rodlike, spiral, or filamentous single-celled body. It grows in colonies or moves by means of long, whip-like appendages called flagella. Some create their own food, absorb dissolved organic material, or feed on the host organism. Bacteria are important to humans because of their chemical effects, and because they often cause disease. (Webster's, 1991) Simply put, they are microscopic plants or animals, some of which have the ability to cause disease in humans if provided the correct environment. Sometimes they are referred to as microorganisms.

9.8.1.2 Sterilization

Sterilization means a chemical or physical treatment which inactivates (killing or inhibiting reproduction) all living and vegetative microorganisms.

Strictly speaking, absolute sterility does not exist and it should in fact be expressed in terms of "probability of survival". In other words, given a certain initial bacterial load, one evaluates the probability of finding still viable microorganisms after a specific sterilization treatment.

With sterile disposable devices, for example, a survival probability of 10^{-6} is commonly accepted, which equals one contaminated device in a million.

The more reduced initial contamination is, the lower the risk of residual contamination after a sterilization treatment.

9.8.1.3 Disinfection

Disinfection means the chemical or physical process which affects living microorganisms, but has little efficacy on vegetative forms. Taking into account that a large part of the microorganisms pathogenic to man do not have vegetative forms (spores), disinfection is a treatment which because of its simplicity and rapidity may prove useful in numerous situations of prevention of microbic contamination. In the hospital environment, or more precisely, in departments with a high risk of contamination, prevention and prophylaxis are certainly a standard to pursue to obtain a level of quality which will produce greater benefits to the patient, the hospital staff and the society. The problem of disinfection is particularly critical during dialysis, where a large

quantity of blood comes into contact with the external environment, even if through specially prepared circuits.

9.8.2 Bacteria in Dialysis Systems

Gram-negative bacteria (those that do not hold the purple dye when stained by the process called Gram's stain) live and can multiply in water, even in DI (deionized) or RO (reverse osmosis) water, which has only small amounts of organic matter. Gram-negative bacteria can develop with tremendous speed in the water and dialysate, encouraged by the presence of dextrose and by the heating of the dialysate. Levels of contamination can range from 102 to 106 CFU (colony forming units) per milliliter in water (AAMI, 1990, pp. 81-94) and can cause pyrogenic reactions (such as fever, shaking, rigors, lowered blood pressure) and/or septicemia (blood poisoning) (Favero, 1985, and AAMI, 1990, pp. 81-94).

Table 9-9 lists some types of Gram-negative bacteria found in dialysis systems.

Table 9-9. Water-Born Bacteria Found in Hemodialysis

Pseudomonas	Achromobacter
Flavobacterium	Aeromonas
Acinetobacter	Serratia
Alcaligenes	Moraxella

9.9 BACTERIA CONTAMINATION

9.9.1 Contributors

Table 9-10 is a list of elements influencing the total bacteria count of the water in a hemodialysis system (Favero, 1985, and AAMI, 1990, pp. 81-94). Even water that is chlorinated by water treatment facilities can contain low levels of microorganisms.

Table 9-10. Contributors to Bacteria Growth

Element	Comment
Water Supply Source	
1. Filtration	
a. particulate filter	Prefiltering used to protect the dialysis machine, but does not remove microorganisms and can increase bacteria levels.
b. absolute filters	Membrane types. Temporarily removes bacteria, but clogs. Gram-negative bacteria can grow through filter. Need frequent replacement and disinfection.
c. activated carbon filter	Does not remove bacterial endotoxin. Removes organics and available chlorine. With chlorine removed from water, it becomes a reservoir for bacteria growth.
2. Water treatment devices	
a. softeners & deionizers	Both are reservoirs for bacteria and they do nothing to remove the bacterial endotoxin.
b. reverse osmosis	Removes bacteria and endotoxin, but must be disinfected frequently; requires high water pressure.
c. ultraviolet light	Endotoxin not affected and UV-immune bacteria can grow.
d. ultrafilter	Membrane similar to RO, but operates on normal line pressure. Less proficient in removing organics or salts. When positioned as a last step in treatment process, will remove bacteria and endotoxin.
Distribution System	Inside diameter and length can provide spaces where bacteria can grow if larger or longer than necessary.
3. Water & dialysate distribution lines	
a. size and length	
b. construction quality	Bacteria growth will be caused by bad joints, dead spaces, and unused branches.
c. outlet tap's elevation	Prevent loss of disinfectant by locating as high as possible.
4. Storage tanks	Can provide reservoir for water bacteria. Need regular disinfection.
Dialysis Machine	All fluid and exposed parts of the machine should be disinfected regularly.

Water processed by the various components of the water purification system to remove harmful chemicals including chlorine can encourage bacteria growth due to the absence of the chlorine (AAMI, 1990, pp. 81-94).

Most equipment used for water purification does little to decrease the bacteria. In some cases, the water purification system can increase the total microbial contamination count. This is especially true when filters are not changed when required or when recommended disinfection procedures are not being followed.

Reverse osmosis systems remove most of the bacteria, viruses, and endotoxins, but low numbers of Gram-negative bacteria can grow downstream. Routine disinfection is required to keep the bacteria levels minimized (AAMI, 1990, pp. 81-94).

When the water is proportioned with concentrates, the resulting dialysate becomes the food required by bacteria to increase growth dramatically. Gram-negative bacteria growing in distilled, deionized, or reverse osmosis water can reach levels of 10^5 to 10^7 cfu/mL. In contrast, these same bacteria growing in dialysis fluids achieve levels of 10^8 to 10^9 cfu/mL (AAMI, 1990, pp. 81-94).

9.9.2 Allowable Limits

Standards set by the Association for the Advancement of Medical Instrumentation (AAMI) and the US Food and Drug Administration (FDA) state that 200 cfu (colony forming units)/mL is the maximum allowable bacterial concentration in product water used for dialysis purposes. ***AAMI RD62: 2001 has also added an action level of 50 cfu/mL. If the test is above 50, an action must be taken (such as disinfection of the loop and RO system and reculturing).***

The AAMI standard also states that the total microbial count in proportioned dialysate should not exceed 2,000 cfu/mL.

It further directs that voluntary endotoxin (lipopolysaccharide) levels in water used for reuse shall not exceed 1 ng/mL as demonstrated by the Limulus amebocyte lysate (LAL) assay. ***In the AAMI RD62: 2001 LAL testing is no longer voluntary. It is required for all water used for dialysis purposes and should not exceed 2 EU(endotoxin units)/mL with an action level of 1 EU/mL.***

If the dialysate or the water used to prepare it exceeds the allowable limit for bacteria and endotoxins, the dialysis patient can exhibit clinical signs such as shaking, chills, fever, hypotension, myalgia, nausea, and vomiting (pyrogenic reactions) and possible

sepsis. The onset of these symptoms usually occurs one to two hours after initiation of the treatment, *but may happen as early as one-half hour*.

9.9.3 Responsibilities

AAMI states that the "physician in charge of dialysis" or the "medical professional" appointed by the physician is responsible for monitoring the water for levels of contamination (AAMI, 1990, pp. 55-58). This is often the service person.

Sampling for bacteria levels of water and dialysate should be accomplished at least monthly (AAMI, 1990, pp. 55-58). This requires taking a sample of not only the incoming water supply to the dialysis machine, but also a sample from each dialysis Instrument (see Section 9.9.1). Additionally, repeat samples must be taken when evidence of contamination exceeds the maximum allowable level or when patients exhibit pyrogenic reaction or septicemia (AAMI, 1990, pp. 55-58). Pyrogenic reactions are primarily shaking and rigors accompanied by lowered blood pressure (AAMI, 1990, pp. 81-94).

Home patients can sample less frequently if the patient is considered reliable and the levels of contamination are always below the recommended levels (AAMI, 1990, pp. 55-58).

The supplier of the water system is responsible at the time of installation or initial qualification to provide equipment that meets or is below the maximum safe contamination levels, or standards specified by the physician at the time of initial qualification (AAMI, 1990, pp. 55-58).

The supplier of water equipment is also responsible for recommending a method of disinfection that continually produces culture test results at or below the prescribed standards (AAMI, 1990, pp. 46-47).

After installation of the equipment, the physician or his appointee is then responsible for maintaining recommended safe contamination levels (AAMI, 1990, pp. 55-58).

9.10 DISINFECTION VERIFICATION

9.10.1 Culture Sampling

The bacteriologic test is a quantitative test and not a qualitative test (AAMI, 1990, pp. 81-94). We need to know the total amount of bacteria present in the water or the hemodialysis system. Disinfection procedures discussed in this section deal only with the presence of bacteria over the maximum allowable limits in water or dialysate, not with the types of bacteria present.

The Association for the Advancement of Medical Instrumentation (AAMI) recommends monthly sampling of the water treatment system or when clinical indications suggest pyrogenic reactions and/or septicemia (AAMI, 1990, pp. 55-58). If previous test results exceed maximum limits or there have been changes in the disinfection procedures, samples should be repeated (AAMI, 1990, pp. 81-94).

Initial water samples should be taken at a point where it enters a proportioner (AAMI, 1990, pp. 81-94) or just before it enters a Baxter hemodialysis system. This ensures all upstream components of the water system be considered as areas where bacteria may be growing. Samples taken before this point may not show a contamination if only the feed line to the machine was the source of the bacteria.

Samples should be taken at each supply point throughout the water distribution system to assure complete sampling. This is particularly true if patients are displaying pyrogenic reactions, disinfection procedures have changed, or previous samples were outside acceptable limits.

9.10.1.1 Water Supply Sample Collection

1. Attach a clean (see Note 1) 1/4" ID hose to the water supply.
2. Open the water supply at full force and do a high velocity flush of the hose for about 1 minute.
3. Reduce flow to a controllable flow rate.
4. Using aseptic technique, draw a clean sample into an appropriate, clean container (see Note 2). Seal the container immediately after taking the sample.
5. Wipe the exterior of the container with an alcohol swab. Send the sample to the lab for analysis immediately, or refrigerate and assay within 24 hours.

NOTE 1

Containers, connectors, and hoses used for collection of samples for microbiological analysis should be routinely cleaned and disinfected. Soak in 200 ppm solution of bleach (0.5 ml of 5.25% sodium hypochlorite solution per 100 ml RO water) for 10 minutes. Rinse with RO water. Allow to air dry and store in a clean, dry area.

NOTE 2

Because the dialysate and water connectors can be touched with the hand and/or are exposed to air when opened, it is important that a mid-stream sample be taken. Flush for 30 seconds prior to taking the sample (Bland & Favero, 1990). This will ensure a sample that reflects the true condition of the fluid pathway.

AAMI recommends sampling hemodialysis Instruments monthly or when clinical indications suggest pyrogenic reactions and or septicemia (AAMI, 1990, pp. 55-58). Dialysis fluid samples should be taken at a point after the fluid leaves the dialyzer and after the Instrument was used for a treatment (AAMI, 1990, pp. 81-94).

9.10.1.2 Dialysate Sample Collection

1. Enter Rinse Mode.
2. Press the manual bypass switch to stop flow in the dialysate lines.
3. Disconnect the “to dialyzer” dialysate line (blue cap) from the Instrument.
4. Without touching the dialyzer connector opening or surrounding area, hold the connector over the fluid catchall container, a sink, or a basin in such a manner that the stream will flow straight out of the bottom of the connector. (See Figure 9-1.)

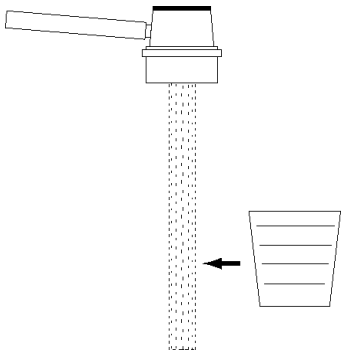


Figure 9-1. Sample Collection

5. Press the manual bypass switch to start flow through the dialyzer line.
6. Let the system flush in this manner for 30 seconds.
7. Move the sterile sample container into the stream and aseptically collect a liquid sample.
8. Repeat Step 7 to collect a second sample.
9. Press the manual bypass switch to stop flow in the dialysate lines.
10. Connect the dialysate line to the Instrument.
11. Press the manual bypass switch to start flow in the dialysate lines.
12. Aseptically seal the sample containers with the lids.

9.10.2 Laboratory Procedures

All samples should be assayed within 30 minutes of collection or refrigerated and assayed within 24 hours. Microbiological assay of the sample should be by the pour plate technique, spread plate technique, or membrane filtration. If the spread plate technique is used, the sample should be quantitatively measured with a pipette and not a calibrated loop (Bland & Favero, 1990). The calibrated loop measurement currently being used by many laboratories does not meet AAMI standards for determining culture counts in water or dialysate.

Standard plate counts are the objective of the survey (AAMI, 1990, pp. 81-94). Colonies should be counted after incubation for 48 hours at a temperature of 37° C (AAMI, 1990, pp. 81-94). If the testing is for non-tuberculous myobacteria, the culture should be incubated for 5 to 7 days (AAMI, 1990, pp. 81-94).

9.11 CENTRAL CONCENTRATE DELIVERY SYSTEMS

Sometimes a white sticky substance may appear in the tubing of hemodialysis Instruments. The source of this substance could be the "coily" concentrate tubing used to connect to central Acid and/or Bicarbonate delivery systems. If you are using the translucent red, blue or clear polypropylene coily tubing, it will be damaged by acidic cleaning solutions.

The manufacturers/distributors of this tubing recommend that you use the PVC version (clear only) if you are using acidic chemicals to disinfect or decalcify your Instruments. This would include chemicals like Actril, Renalin, and vinegar.

Please note that concentrate lines longer than the standard will add volume to your systems and may affect ALL dialysis machines. For chemical disinfection/cleaning, the time required to rinse any chemicals may be longer. You can extend the programmed rinse time in Service Mode as needed.

9.12 MAINTAINING MINIMUM BACTERIA GROWTH LEVELS

Once bacteria has a chance to establish itself in a system, it is hard to remove. The best course of action is to prevent colonization and the subsequent growth before it starts. Table 9-11 lists actions to prevent bacteria from becoming established.

Table 9-11. Preventing Bacteria Growth

Action	Comments
Water treatment system design and construction	Poor design can lead to continual bacteria growth.
Routine maintenance	Disinfect or replace components when required.
Monthly cultures	Show trends and highlight problem areas.
Routine disinfection of water system	Keeps levels under control
Test results and maintenance records kept up to date	Can show trends and highlight problem areas
Disinfect Instrument before use.	Kills residual bacteria before patient use
Never expose the Instrument to tap water.	Tap water will introduce bacteria to the Instrument's internal fluid system.
Isolate Instrument from drain.	Prevents growth through drain hose when Instrument is not operating
Disinfect bicarbonate containers and dip tubes daily.	Bicarbonate promotes bacteria growth.
Disinfect acidified concentrate containers and dip tubes monthly.	Eliminates this bacteria source
Quarterly full-system disinfect	Cleans entire Instrument

9.13 TROUBLESHOOTING BACTERIA PROBLEMS

When troubleshooting for bacteria problems, it is important to find the source and cause of the problem, not just treat the symptoms.

Use a systematic approach when troubleshooting. Don't attack the problem randomly. Don't change components because they are suspected, or the new components could also be contaminated. Also, there could be more than one source or cause of contamination. They all must be found and eliminated one by one to prevent recontamination.

Contaminated upstream systems and components will contaminate downstream. To troubleshoot properly, start analysis at the furthest downstream point and work upstream, but take correct actions starting at the front end of the system and working downstream. This prevents recontamination downstream.

Before starting troubleshooting, gather all the data available about maintenance techniques, procedures, quality control, and any recent changes. Take water samples and have them assayed for indications of the extent of the contamination.

The goal is to find the cause of the problem, correct it, and make sure it does not happen again.

To troubleshoot properly, you must:

- Gather all test data and maintenance records.
- Identify all the systems that can contribute to bacteria growth.
- Examine the symptoms.
- Analyze all the information.
- Locate the source and cause of the contamination.
- Take corrective action.

9.13.1 Gather Data

Maintenance records can point out faulty or missing procedures and document activities as they take place. For instance, if a filter was supposed to be replaced monthly and the records show this was not done, then the filter could be the main source of the problem.

Previous test results can display potential problem areas so you can go back and test these areas again to see if levels at these points

have increased beyond recommended levels. Increased levels give clues where the problem source may be located.

A water treatment system diagram marking all possible sampling site locations can be of a tremendous benefit. By identifying each sample site with a number and assigning that number to each sample taken, it would be easier to locate a problem source. Trend analysis also can be accomplished with this information and potential problems be averted before developing further. Historically, some aspect of the water treatment system has proven to be the major cause of contamination. Test results that indicate high microbiological contamination in the dialysis machine but no contamination in the water treatment system often indicate that a premachine source of contamination has been overlooked.

The time that samples are taken could be an important clue. Samples immediately following disinfection are not going to be a good indicator of adequate disinfection. But, if done and they show signs of contamination, this would be reason to suspect problems with the disinfection procedure or dead legs in the distribution system. High levels of bacteria found shortly after disinfection could point out the need to disinfect more frequently or to replace filters more frequently.

Check the process of taking samples to ensure an aseptic technique is used to avoid contaminating the sample. Make sure the sample is taken mid-stream, after about 30 seconds of flow (Bland & Favero, 1990).

Samples must be assayed within 30 minutes or refrigerated and assayed within 24 hours (AAMI, 1990, pp. 81-94).

Take new samples before starting to analyze the problem. This will give a base line to make comparisons of past and future data.

Make sure the lab is using the proper technique for assaying the samples. A pour plate, spread plate, or membrane filter technique should be used (AAMI, 1990, pp. 81-94). Make sure the measurement is done via pipette versus the calibrated loop method (Bland & Favero, 1990). The culture medium should be trypticase, soy agar, or standards methods agar, and incubation should be at 37° C. The colonies should be counted after 48 hours. The objective of the assay at this point is to find the total bacteria count (AAMI, 1990, pp. 81-94).

9.13.2 Identify Contributors

The city water systems can always be considered a contributor as small amounts of bacteria may always be present. However, with

a properly designed water treatment system, most of this bacteria can be removed or controlled.

The center's water treatment system is usually where the contamination starts when there is a problem. This is because factors influencing growth can be complex. All of the components of the water treatment system, given the right circumstances, can promote bacteria growth.

The hemodialysis system, by being at the furthest downstream point, is easily contaminated. The internal pathways are complex and can serve as reservoirs of contamination.

The dialysis concentrates are acetate, acid, and bicarbonate. Acetate and acid are normally not a problem, but bicarbonate is food for the bacteria and supports rapid bacteria growth.

The dialyzer and dialyzer reprocessing system also must be looked at as a potential contributor to bacteria contamination. If the reprocessing system becomes contaminated, it could contaminate the dialyzer and in turn, the hemodialysis Instrument.

9.13.3 Examine the Symptoms

An important clue as to where the source of the problem exists is the type of patient symptoms reported or measured. For instance, high bacteria counts of less than 2,000 cfu/mL may be acceptable from the hemodialysis Instrument, but not from the water system. Find out exactly where high counts are experienced. Know what is acceptable and what is not.

If counts are randomly high from the water system, then investigate what is different when they go high versus when tests are normal. Decide if the symptoms exist at all feed lines, all hemodialysis Instruments, or if the symptoms are localized to a specific area.

Are patients exhibiting pyrogenic reactions? Are they random and isolated, or consistent and localized? Find out the type of symptoms experienced, the time the episode started, and the length of the episode. These important questions can tie the outbreak into some change made in procedures.

9.13.4 Analyze

Analyze all the information collected to localize the outbreak to a contributor system or systems. Clues should be obvious in identifying systems that are contaminated, but it may not be as easy to identify the source and/or cause of the bacteria

contamination. The cause of the outbreak must be found and eliminated.

Separate the information by system and analyze it on the contaminated systems. Look for clues to find the source and/or cause of the bacteria growth.

9.13.5 Look for the Source and Cause

The objective of gathering and analyzing all this information is to locate the cause of the contamination and to take proactive measures to guarantee this will not be the cause of any future outbreaks. This is the way systems, procedures and techniques are improved and bacteria growth is minimized.

For instance, if the problem is specific to the hemodialysis machine, investigate the following:

Sampling

- Using aseptic techniques
- Disinfection of sample site
- Flushing before taking samples
- Sample site in path of disinfection
- Samples assayed promptly
- Correct lab procedures and techniques correct

Other contributors

- Treated water bacteria levels above 200 cfu/ml
- Use of non-treated water supply
- Instrument drain line not isolated from drain
- Excessive bicarbonate storage time after mixing
- Disinfection of bicarbonate, concentrate and disinfectants
- Dialyzer not reprocessed correctly (contaminated)
- Poor microbial quality of the water used to prepare the bicarbonate concentrate

Disinfection procedures and techniques

- Following manufacturer's recommendations
- Frequency of disinfection
- Type of disinfectant
- Preparation

- Dwell times
- Concentration of disinfectant

Routine maintenance

- Following hemodialysis machine manufacturer's recommendations

If the contributor to the hemodialysis Instrument's contamination is the water treatment system, check the following to determine the cause:

Water treatment system design

- Type

  Recirculates, holding tank, direct feed
  Any holding tanks are strong suspects because of the time given for growth
  Location of carbon tanks and filters
  Dead legs in distribution lines
  D. I. tanks, common bacteria source

- Membrane

  Type
  Age
  Disinfection/cleaning procedures
  Current flow and rejection rates

- Filters

  Type
  Age
  Disinfection/replacement procedures

- Water treatment system operation

  Recent changes
  Long stagnation times (non-use)

- Maintenance

  Sample techniques
  Disinfection procedures
  Contamination from softeners, carbon beds, other filters

- Station sites infrequently used

The above causes of bacteria contamination are only a few of the many possibilities that exist. Each unit has different water treatment systems, dialysis machines, city water, disinfection chemicals, dialysis concentrates, etc.

Each unit should take a look at its own systems and design a list of potential causes for bacteria contamination. This action would save hours of work later and provide immediate benefit by highlighting current procedures or techniques needing improvement.

9.13.6 Taking Corrective Action

Once the real cause has been removed and procedures updated to prevent recurrence, routine maintenance should be performed, all systems disinfected, and samples taken until all samples are normal.

Frequent samples should be taken until they confirm that the bacteria cause has been eliminated. This procedure is especially beneficial when there is more than one cause of contamination.

9.14 REFERENCES

Bland, L, Carson, L., Ridgeuy, M., Ageuro, S., & Favero, M. (1987). Potential bacteriologic and endotoxin hazards associated with liquid bicarbonate concentrate. *ASAIO Transactions, 33*, 542-545.

Bommer, J., & Ritz, E. (1987). Water quality – a neglected problem in hemodialysis. *Nephron, 46*, 1-6.

Ebben, J. P., Hirsch, D. N., Leuhmann, D. A., Collins, A. J., & Keshaviah, P. R. (1987). Microbiologic contamination of liquid bicarbonate concentrate for hemodialysis. *ASAIO Transactions*, *33*, 269-273.

Favero, Martin S. (1985). Dialysis-associated diseases and their control. In: J. V. Bennett & P. S. Brachman, Eds., *Hospital infections*, 2nd Ed., 267-284. Boston: Little Brown. [There is a 1992 edition ISBN 0316089907 with this article on pages 357-380]

Favero, M. S., Peterson, N. J., Boyer, K. M., Carson, L. A., & Bond, W. W. (1974). Microbial contamination of renal dialysis systems and associated health risks. *Transactions American Society for Artificial Internal Organs, 20,* 175-183.

Hemodialysis systems. (2003). ANSI/AAMI RD5:2003. Arlington, VA: Association for the Advancement of Medical Instrumentation.

National Institute for Occupational Safety and Health. (1981). *Current Intelligence Bulletin 34: Formaldehyde: Evidence of carcinogenicity* (DHHS Publication No. 81-111). Washington, DC: U. S. Government Printing Office

Rafter, T.,& Brodeur, F. (Summer, 1987). A replacement for formalin. *CANNT Journal*, 13-15.

Water treatment equipment for hemodialysis applications. (2001). ANSI/AAMI RD62:2001. Arlington, VA: Association for the Advancement of Medical Instrumentation.

Webster's Ninth New Collegiate Dictionary. (1991). Springfield, MA: Merriam-Webster.


Arena

REV	ECO #	DESCRIPTION	APPROVED	DATE

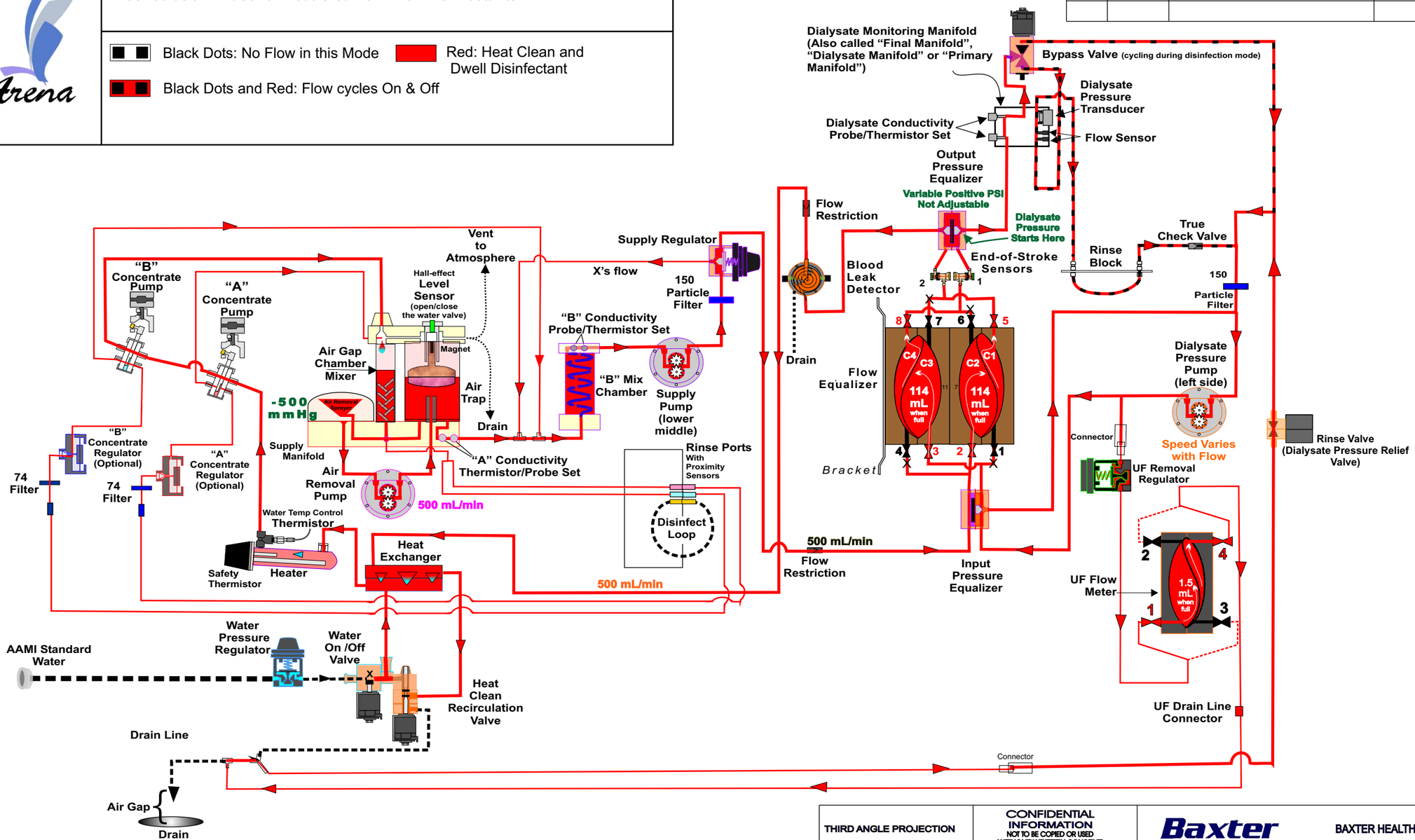
Disinfection Mode

Recirculation Phase for Heat Clean or Dwell Disinfectants

Black Dots: No Flow in this Mode

Red: Heat Clean and Dwell Disinfectant

Black Dots and Red: Flow cycles On & Off



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	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. TOLERANCES ARE: DECIMALS .XX ± .01 .XXX ± .005 ANGLES ± .5^	DESCRIPTION: Arena Hydraulics Disinfection Mode Diagram	
	SURFACE FINISH: 63	MATERIAL / FINISH / SPECIFICATIONS	DWG No. B ▫ 157-1278-938 REV A
	DO NOT SCALE DRAWING BREAK ALL SHARP CORNERS .005/.010 CHAMFER/RADIUS		DRAFTER K.Austin DATE 3-02-04 SCALE None SHEET 1 OF 2

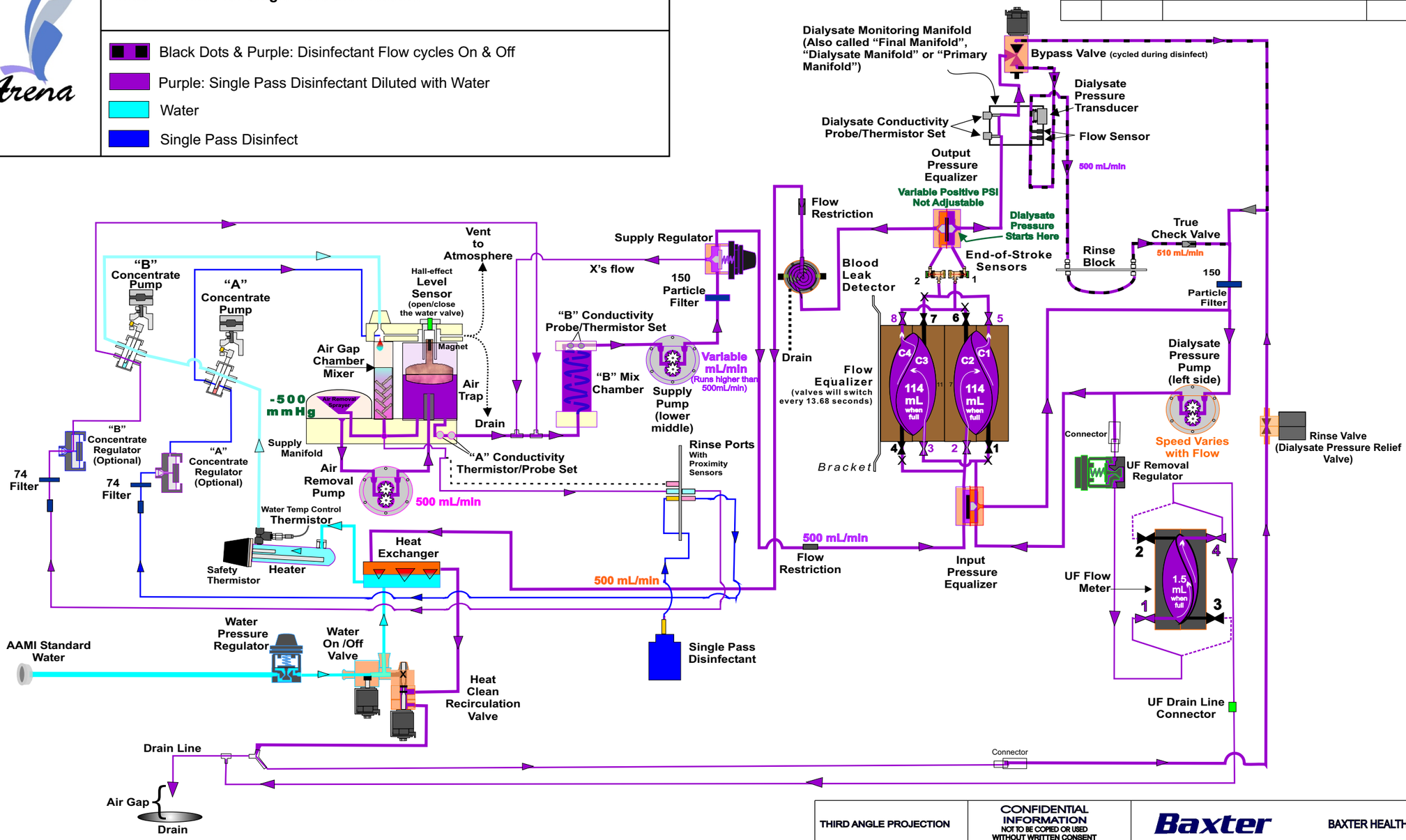
CorelDRAW FILE

REV	ECO #	DESCRIPTION	APPROVED	DATE

Disinfection Mode

Infusion Phase for Single Pass Disinfectants

- Black Dots & Purple: Disinfectant Flow cycles On & Off
- Purple: Single Pass Disinfectant Diluted with Water
- Water
- Single Pass Disinfect



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	SURFACE FINISH: 63	MATERIAL / FINISH / SPECIFICATIONS
	DO NOT SCALE DRAWING BREAK ALL SHARP CORNERS .005/.010 CHAMFER/RADIUS	DWG No. B ▫ 157-1278-938 REV A DRAFTER K. Austin DATE 03-02-04 SCALE None SHEET 2 OF 2
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Arena

10. BLOOD PUMP CONTROL SYSTEM

10.1 OVERVIEW

The blood pump is a peristaltic pump that moves extracorporeal blood at the prescribed flow rate during dialysis. During extracorporeal alarms, the blood pump stops, occluding the pump segment of the arterial blood tubing and preventing any more blood from being drawn from the patient.

The blood pump control system includes the following components:

- Single Board Computer (SBC)
- Blood pumps, primary and (optional) secondary, including motor, optical speed sensor, and rotor
- Blood Pump Controller Board for software speed error control
- Blood Pump Power Board for hardware speed error control and motor power driver circuitry
- Venous line clamp (VLC), including VLC optical sensor, and I/O Controller and Power Boards.

The following are also involved with this system:

- Extracorporeal arterial and venous blood pressure measurement (see Section 12.1.1 and 12.1.2)
- Drip chamber level adjust controls, including motors, valves and switches (see Section 12.1.3)
- Heparin delivery system (see Section 11, Heparin Delivery)
- Internal cabinet temperature control (see Section 6.5).

All Arena Instruments include the primary pump. The secondary pump is included only if the Single Needle or OLHDF Options are included with the Instrument. Refer to Section 22, Single Needle, and Section 24, Hemodiafiltration/On-Line HDF, for more information on these options.

10.2 PRIMARY AND SECONDARY BLOOD PUMPS

The primary and optional secondary blood pumps are mechanically and electrically identical. The Blood Pump (BP) assembly consists of the following elements (see Figure 10-1), most of which are internal to the Instrument:

Mounting Plate. Helps to correctly attach and position the BP assembly in the Instrument.

Gear Box with Spindle. Transmits the rotary motion of the DC Motor to the BP Rotor (see Figure 10-1) providing the appropriate change in speed and torque. You can gain speed or torque at the expense of the other.

Canted Coil Spring. Mounted on the Spindle, it holds the Rotor assembly in place.

DC Permanent Magnet (Brush-type) Motor. This type of motor uses a permanent magnet to generate the magnetic field in which the armature rotates. Torque is an inversely proportional linear function of speed. At the same time, speed is proportional to voltage and torque is proportional to current; therefore, any increase in the BP torque will be accompanied by a corresponding decrease in speed or vice versa as long as the total BP power remains the same.

This is a reliable, low-cost motor that can produce high starting torque and can be decelerated rapidly. In particular, the ability to quickly decelerate the motor is important because in case of an extracorporeal alarm, the BP must immediately stop rotating to isolate the patient from the Instrument.

Tachometer (Optical Sensor). Measures the speed of the motor. See Section 10.5 for more information.

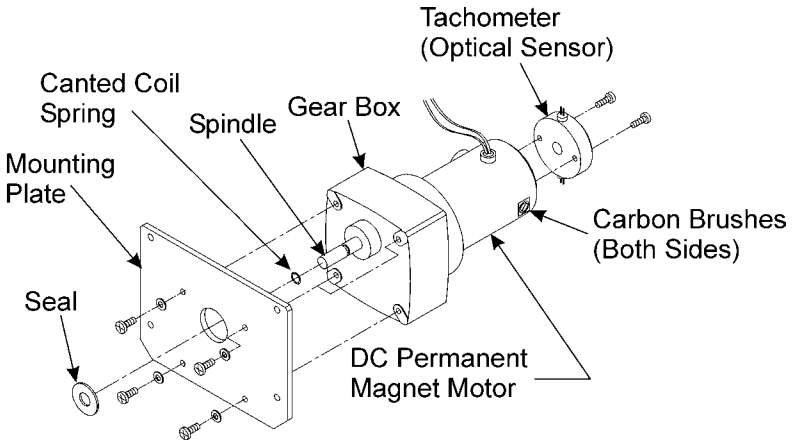

Figure 10-1. Blood Pump Assembly

The external elements are the doors and reed switches (see Section 10.3), and the Rotor assembly (see Section 10.4).

The BP can use different sizes of blood tubing. The size must be selected and the rotor occlusion calibrated by a certified technician. Refer to Sections 17.3.1.3 for tubing size selection, and 18.6.1 and 18.6.2 for calibration.

10.2.1 Primary Blood Pump

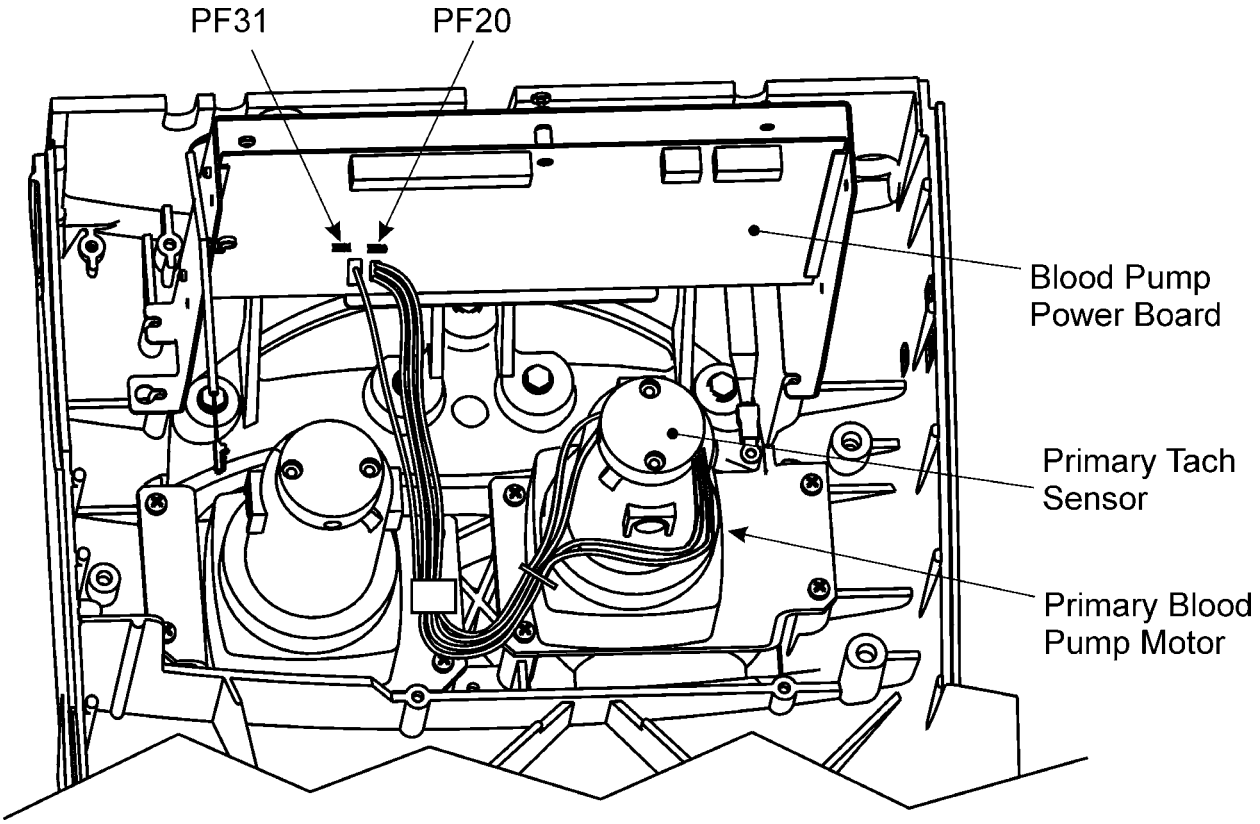

Figure 10-2. Primary Pump

Table 10-1. Primary Pump Connectors

PF31, Power	PF20, Control
Pin 1, Motor 1, positive	Pin 1, Tach 1
Pin 2, Motor 1, negative	Pin 2, Tach Gnd
Pin 3, not connected	Pin 3, LED Gnd
	Pin 4, LED Power
	Pin 5, Door Switch 1
	Pin 6, Switch Gnd

10.2.2 Secondary Blood Pump (Optional)

Compare Figures 10-1 and 10-2, and notice that the Secondary Pump motor is rotated 90° with reference to the Primary Pump motor.

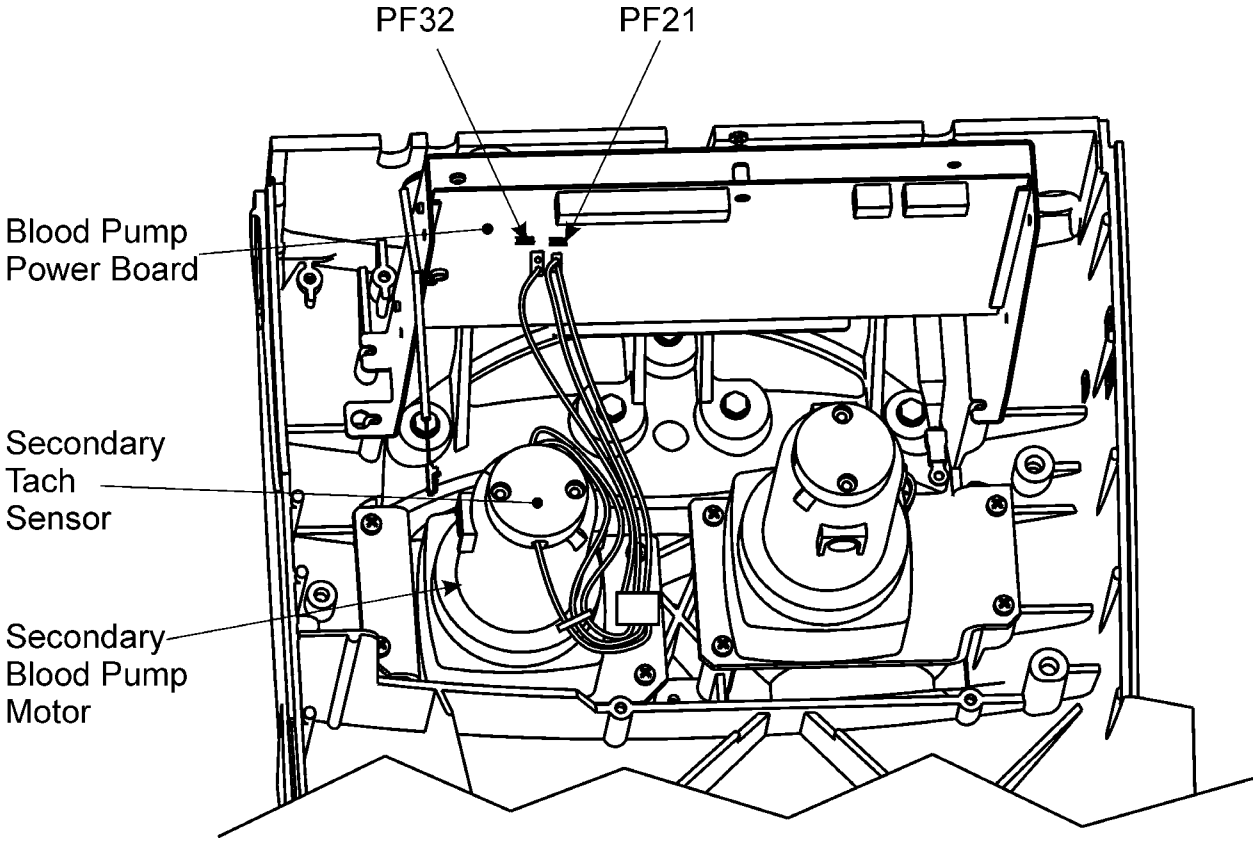

Figure 10-3. Secondary Pump

Table 10-2. Secondary Pump Connectors

PF32, Power	PF21, Control
Pin 1, Motor 2, positive	Pin 1, Tach 2
Pin 2, Motor 2, negative	Pin 2, Tach Gnd
Pin 3, not connected	Pin 3, LED Gnd
	Pin 4, LED Power
	Pin 5, Door Switch 2
	Pin 6, Switch Gnd

10.3 BP DOORS AND SWITCHES

The blood pump doors protect the operator from injury when the BP Rotor is turning. These doors each have a small magnet embedded into the upper corner (see Figure 10-4). A reed switch is mounted inside the Instrument at the same location. The reed switches are connected to the Blood Pump Power Board. (See Tables 10-1 and 10-2.) The state of the reed switch is monitored by the Blood Pump Controller Board via the ribbon cable from the Blood Pump Power Board.

When the door is open, the power board receives a stop signal and the pump will not function. When the door is closed, the power board receives a non-stop signal and blood pump is able to function. If the door is opened when the rotor is already moving, the blood pump will stop immediately and an alarm message will be displayed within 30 seconds. (If the secondary pump is not installed, opening that door will not create an alarm.)

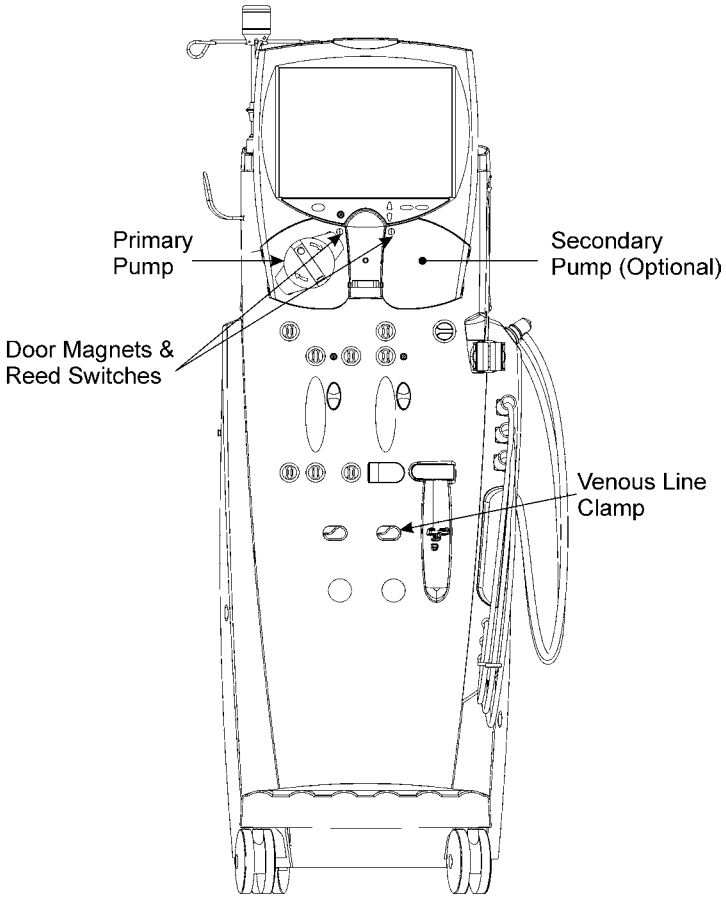

Figure 10-4. Location of Blood Pumps, Venous Line Clamp, and Door Switches

10.4 ROTOR ASSEMBLY

There are seven major parts within the blood pump rotor assembly: handle, rotor body, rollers, roller arms, pivot pins, set screws and springs. (See Figure 10-5).

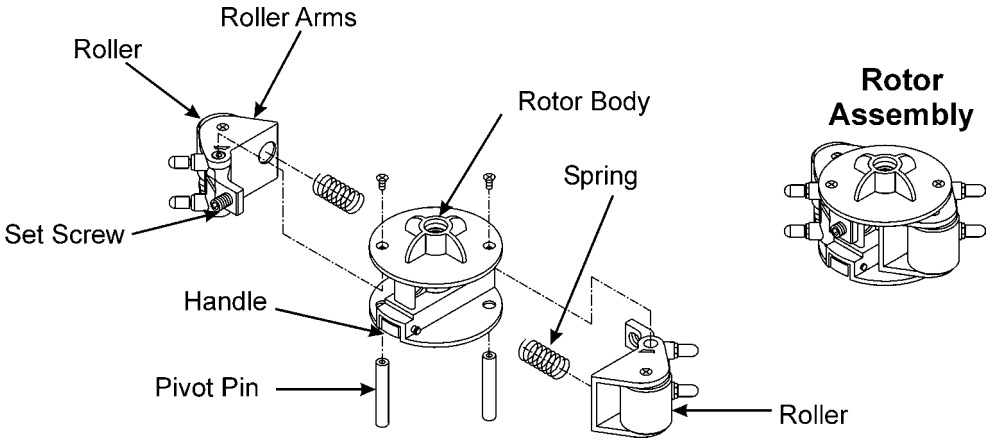

Figure 10-5. Rotor Assembly Exploded View

The handle is mounted on the front of the assembly and can be used for manual pumping.

The rollers are mounted on the roller arm, which connects to the rotor body via a pivot pin. The springs are placed between the roller arms and the rotor.

The springs apply pressure on the roller arm pushing the rollers out from the rotor.

The setscrews are mounted on the roller arm. Adjusting the setscrews limits the outward roller arm travel. When the setscrew is turned clockwise the roller is moved toward the rotor causing less pressure on the tubing segment. When the set screw is turned counter-clockwise the roller is moved outward from the rotor causing more pressure on the tubing segment.

When the roller assembly is adjusted properly the correct pressure will be applied to the blood pump tubing segment.

For more information regarding blood pump adjustment go to Blood Pump Rotor Occlusion, Section 18.6.1.

10.5 BP CONTROL AND POWER

The purpose of the Blood Pump Controller Board is to provide the control signals to the Blood Pump Power Board to operate the blood pumps.

The blood pump control system essentially consists of the BP Controller Board and BP Power Board. The BP Controller Board receives regulated +5 V, +12 V and -12 V through the Passive Backplane. The BP Power Board in turn receives those voltages from the BP Controller via the ribbon cable. The +24 V power is delivered to the BP Power Board from the +24 V unregulated power supply. Refer to Section 5.4.4 for the location and configuration of the BP Controller Board.

Figure 10-6 is a block diagram of the blood pump control system. Refer also to the Arena Interconnect Diagram (157-1278-586) at the end of Section 5, Electronic Theory.

The operator enters the desired blood pump rate information on the video display touch panel. The SBC converts this information to the appropriate motor rate which it then sends to the Blood Pump Controller Board. The Blood Pump Controller Board converts the motor rate information to an analog level and feeds the information to a motor speed controller on the Blood Pump Power Board.

An optical speed (tach) sensor is mounted on the rear shaft of the blood pump motor (Figure 10-1), with an LED on one side of the shaft, and a photo transistor on the opposite side. The shaft has two holes drilled through it. Each hole is perpendicular to the shaft and to the other hole. When the blood pump is rotating, four optical pulses are received per shaft revolution.

This tachometer signal is monitored by both the Blood Pump Power Board and the Blood Pump Controller Board. The Blood Pump Power Board provides quick-responding speed control by comparing the motor speed with the desired speed information from the Blood Pump Controller Board. The result of this comparison is an error signal which provides an input to the motor power driver circuit.

The Blood Pump Power Board provides a +24 V pulse width modulated drive to the motor at a frequency of approximately 30 kHz. This drive is current limit protected to prevent damage in the event of a stalled motor.

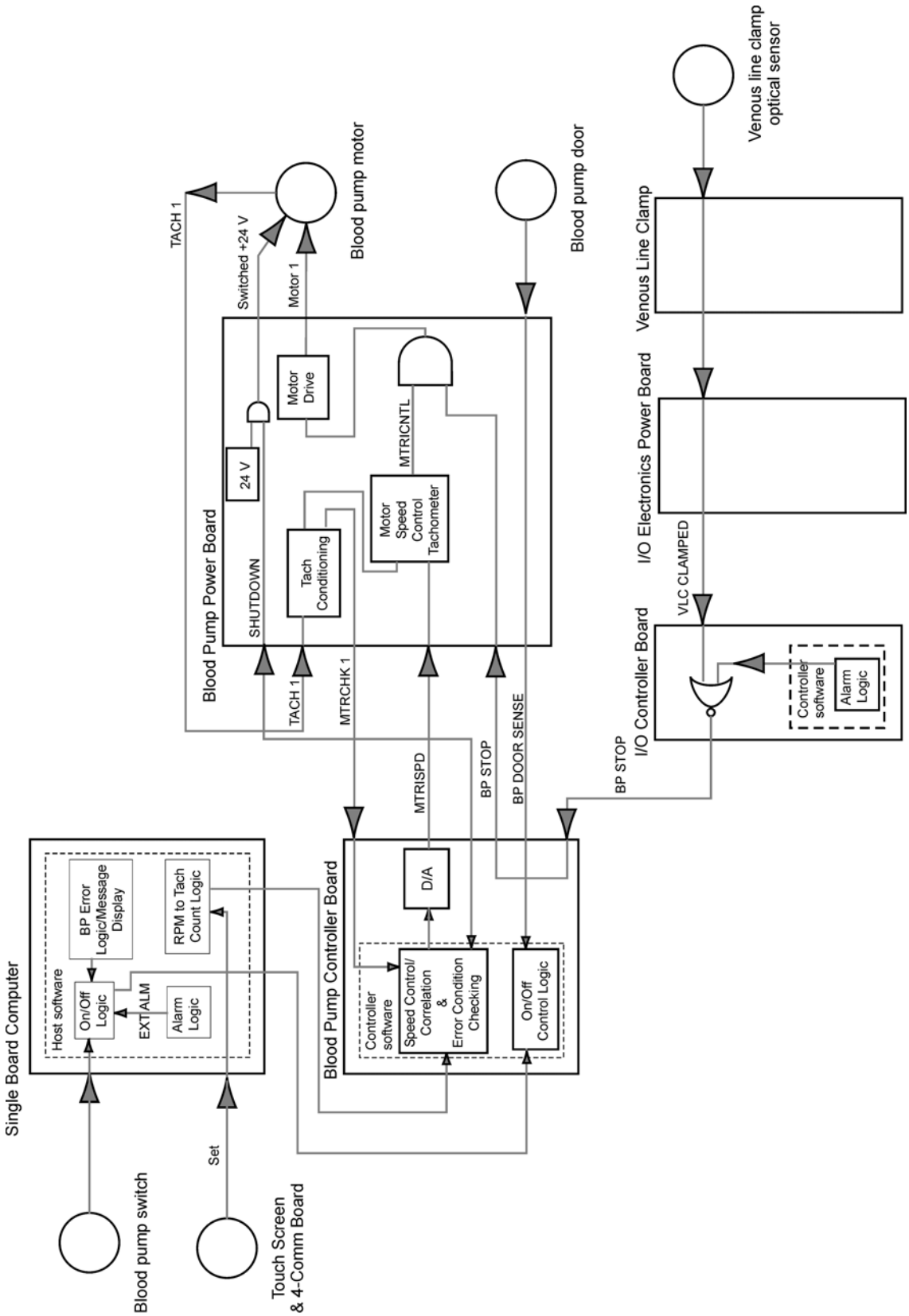

Figure 10-6. Blood Pump Control Block Diagram

The Blood Pump Controller compares the tachometer motor speed information with the desired speed commanded by the SBC and corrects the level provided to the Blood Pump Power Board accordingly. In this way, the Blood Pump Controller guarantees the accuracy of the pump, and the Blood Pump Power Board does not require any calibration. In addition, the Blood Pump Controller monitors for control problems, such as underspeed or overspeed, which may result from failures in the Blood Pump Power Board.

The Blood Pump Controller Board also monitors the motor speed independently of the tachometer signal using the motor's back electromagnetic force (EMF). Periodically (every 0.5 second), the motor drive is turned off for approximately 6 milliseconds and the voltage at the motor terminals is measured. Though this does not result in as precise an indication as the tachometer signal, gross failures can be determined, such as when the tachometer signal is lost or for overspeed detection. The EMF must be calibrated. Refer to Section 18.5.10 for more information on this calibration.

An identical circuit is provided for an optional second blood pump which is used for the Double-Pump Single Needle, Hemodiafiltration (HDF) and On-line HDF options.

10.7 VENOUS LINE CLAMP SYSTEM

The Venous Line Clamp (VLC) system will stop the flow of blood in the venous line of the extracorporeal circuit in case of an extracorporeal alarm (which could come from the Air Detector, the Blood Leak Detector, or the Arterial or Venous Monitors). The VLC system consists of the following elements:

- Venous Line Clamp (linear or rotary)
- VLC Driver Board.

Refer to Figures 10-4 and 10-7 for locations.

10.7.1 Venous Line Clamp

The VLC isolates the patient from the Instrument by blocking the flow of blood from the extracorporeal circuit into the patient (see Section 2.8.2). When power is applied to the line clamp, the occlusion mechanism is pushed forward (linear) or rotated (rotary) causing the VLC to unclamp. When power is removed, an internal spring pulls or rotates the occlusion mechanism causing the VLC to clamp.

Refer to Figure 10-6. When the VLC optical sensor detects that the VLC is clamped, it will send a signal to the BP Controller Board via the I/O Electronics Power Board and I/O Controller Board. The BP Controller will then signal the BP Power Board to stop the Blood Pump. This does not apply if using a Single Needle procedure.

10.7.2 VLC Driver Board

The VLC Driver Board provides power to the linear or rotary VLC. The VLC Driver Board receives 120 VAC from the isolation transformer and coverts it to approximately 180 VDC. When this voltage is applied to the magnetic coil within the VLC, the VLC unclamps. Once the voltage is removed, the VLC clamps due to an internal spring. When the VLC changes state from clamped to unclamped, it draws the maximum current. The peak current for the occurrence is 2.1 A (may vary by line clamp resistance, inductance, and in-line AC voltage). The holding current differs for the two available VLCs. The linear VLC requires a nominal 330 mA and the rotary requires a nominal 480 mA. Selection pins are mounted on the VLC Driver Board (bottom right hand corner, JP4). A two-pin jumper is provided with each board. The position of the jumper depends on the type of line clamp. The two top pins are for the rotary clamp, the two

middle pins are for the linear clamp and the two bottom pins are for storage. See Figure 10-7.

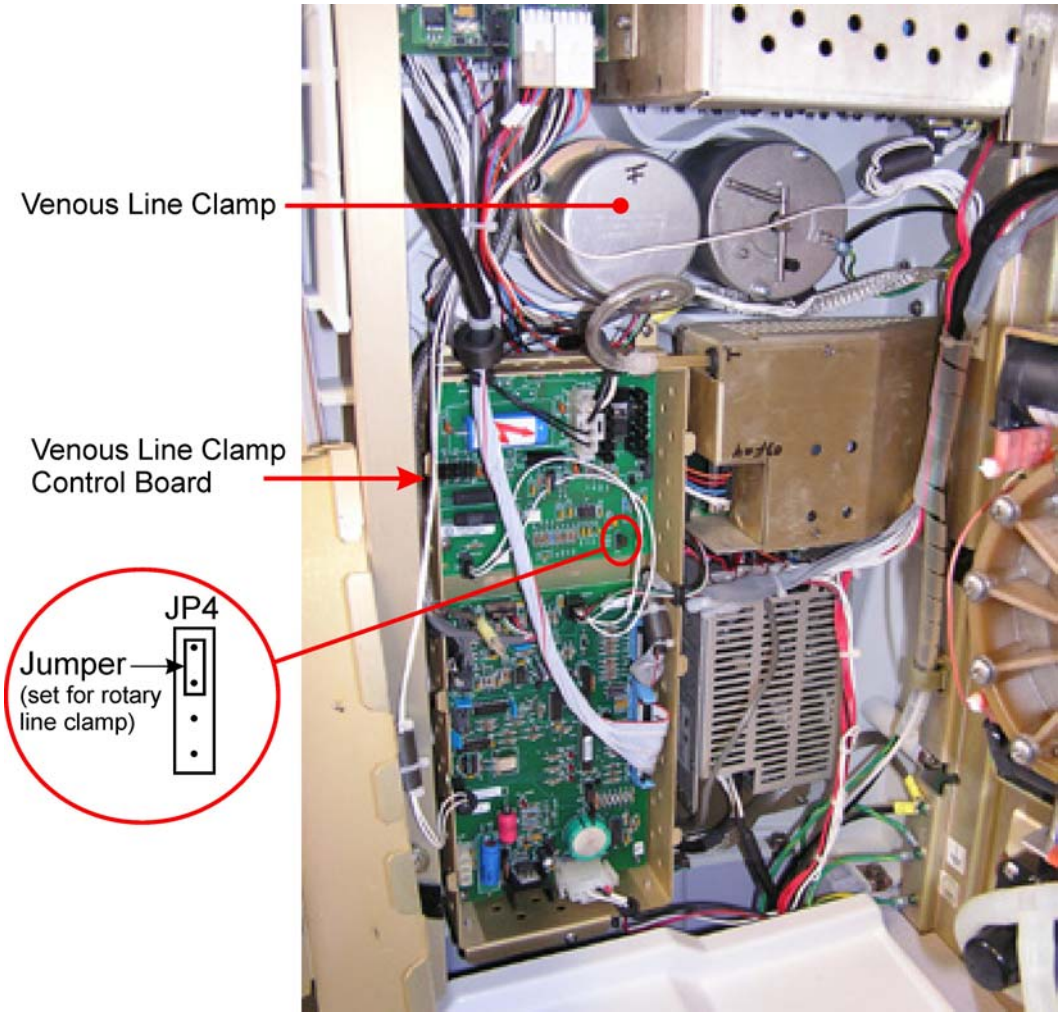

Figure 10-7. VLC Driver Board

10.7.3 Linear VLC Optical Sensor

The VLC optical sensor is mounted on the rear plate of the linear line clamp assembly. The line clamp occlusion mechanism has a small shaft that extends beyond the rear plate when the line clamp is clamped. When the line is clamped, the light from the optical sensor is blocked and the optical sensor's receiver does not sense the light. When the line is unclamped, the shaft is flush with the rear plate and the light from the optical sensor is sensed at the receiver.

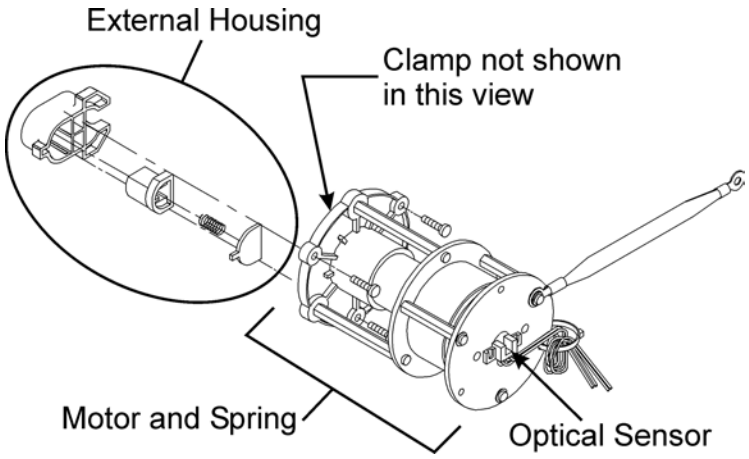

Figure 10-8. Linear VLC

10.7.4 Rotary VLC Optical Sensor

The VLC optical sensor is mounted on the front plate of the rotary line clamp assembly. The line clamp occlusion mechanism has a small shaft attached to it. When the line is clamped, the shaft (actuator) blocks the light on the optical sensor. When the line is unclamped, the shaft moves away from the optical sensor and the optical sensor's receiver senses the light.

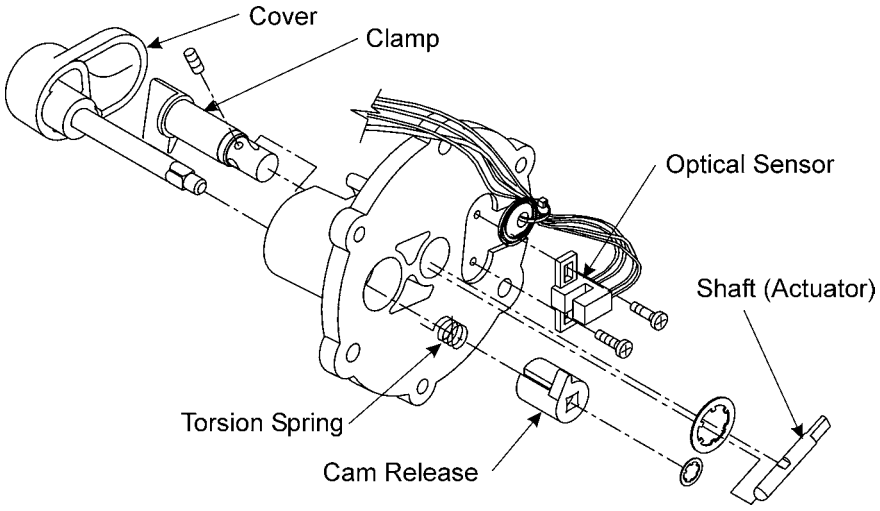

Figure 10-9. Rotary VLC Detail

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11. HEPARIN DELIVERY

11.1 OVERVIEW

Heparin is a chemical that prevents the natural clotting of blood in the extracorporeal circuit. The Arena Instrument can automatically infuse heparin into this circuit at an operator-adjustable rate using a heparin pump.

11.1.1 Customization

A qualified service technician can customize the heparin pump for:

- Maximum Heparin Bolus Limit

The maximum limit is adjustable from 1.0 to 5.0 mL in 1.0 mL increments. Refer to Section 17.3.1.5. The operator will be able to set the bolus volume from 0.3 mL to this maximum value.

- Syringe Size

Sizes allowed are 10 mL, 12 mL, 20 mL or custom capacity syringes. Refer to Section 17.3.1.4. The heparin pump plunger foot must be changed accordingly to switch from a 10/20 to a 20/30 mL syringe or vice versa. See Table 11-1 for a list of the most common syringes and their sizes. B-D's 10 and 20 cc, and Monoject's 12 and 20 cc syringes can be selected directly in Calibration Mode. Other sizes can also be selected using the custom diameter selection.

Table 11-1. Heparin Pump Syringe Reference Table

Manufacturer	Size	I.D. mm
Becton Dickinson (B-D)	10 cc	NA*
Becton Dickinson (B-D)	20 cc	NA*
Becton Dickinson (B-D)	30 cc	21.8
Becton Dickinson (B-D)	30 cc	21.7
Monoject	10 cc	15.7
Monoject	12 cc	NA*
Monoject	20 cc	NA*
Terumo	20 cc	20.1
Terumo	20 cc	20.2
Terumo	30 cc	23.3

*This value is preprogrammed. If the same I.D. is entered for a syringe from a different manufacturer, the manufacturer shown in Column 1 will be displayed.

11.1.2 Usage

For detailed usage instruction, refer to the Operator's Manual. The following is a brief summary:

- The heparin syringe should be installed in the Prime Mode.
- The heparin pump rate may be set in the Prime or Dialyze Mode.
- The heparin pump rate may be set from 0 to 5.5 mL/h.
- Entering non-zero heparin rate turns on the pump. Entering a zero rate turns off the pump. The words ON and OFF will appear above the HEPARIN PUMP window appropriately. The heparin pump may also be turned off automatically up to 2 hours before the end of the treatment by setting the auto-off feature.
- The type of syringe for which the Instrument is calibrated and the volume of heparin infused are indicated in the main Data Report. The Data Report total heparin infused value indicates the volume of heparin infused by the Instrument during the Dialyze Mode.
- To give a heparin bolus, touch the HEPARIN PUMP window then touch the BOLUS and VERIFY buttons. The bolus volume is displayed on the BOLUS button.
- The heparin pump stops during an extracorporeal alarm or when the blood pump is turned off, a heparin bolus will continue with the blood pump stopped.
- The heparin pump will operate while the blood pump is off during Single-Pump Single-Needle operation.
- The heparin pump alarms when the motor is infusing heparin faster than the setting on the device. It also alarms when the heparin syringe is empty, the motor is stalled or the heparin delivery line is clamped.

11.2 PHYSICAL DESCRIPTION

The heparin pump is an electromechanical syringe pump, which consists of the following elements:

11.2.1 Arm and Arm Shaft

The arm is used to hold the syringe in place from the outside so that the syringe body cannot slide or rotate. The arm shaft signals the arm's engage or disengage position by blocking or unblocking the light path of an optical sensor located on the heparin pump assembly (see Figures 11-1 through 11-3).

11.2.2 Slide Assembly

The slide assembly consists of the gear rack, which meshes with the motor gears, and the custom plunger foot for a 10/20 or 20/30 mL syringe. This assembly will push the syringe plunger up to deliver the heparin (see Figures 11-1 and 11-2).

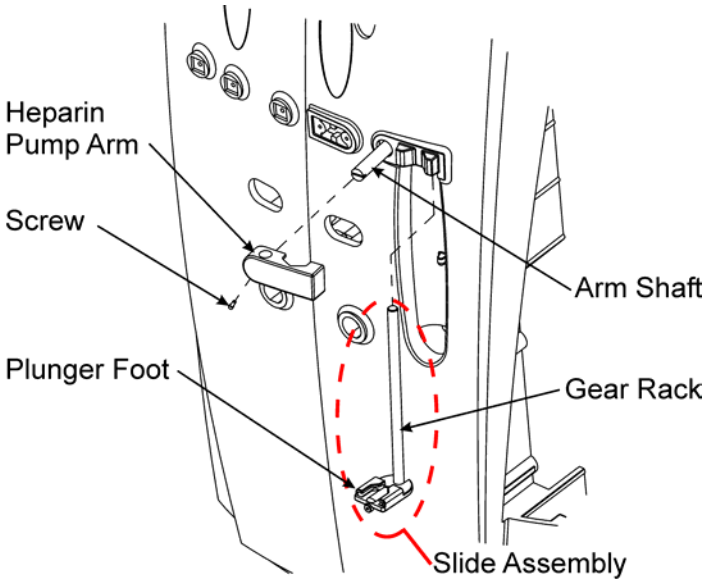

Figure 11-1. External Elements Of The Heparin Pump Assembly

11.2.3 Engage/Disengage Optical Sensor

The arm shaft actuates the engage/disengage optical sensor. When the arm is in the engage position (horizontal), the arm shaft blocks the light reaching the light detector, thereby signaling the engagement. The opposite will happen when the arm is disengaged (vertical). See Figures 11-1 through 11-3. The shaft spring provides the force for the arm to close and hold the syringe body in place.

11.2.4 Motor Pump Assembly

This assembly consists of a DC stepper motor (connected to PF23 in the Blood Pump Power Board), a gear to drive the heparin pump slide assembly gear rack, and one optical sensor for the heparin pump overpressure alarm. This assembly is located behind the Peripheral Interface Board. See Figures 11-2 and 11-3.

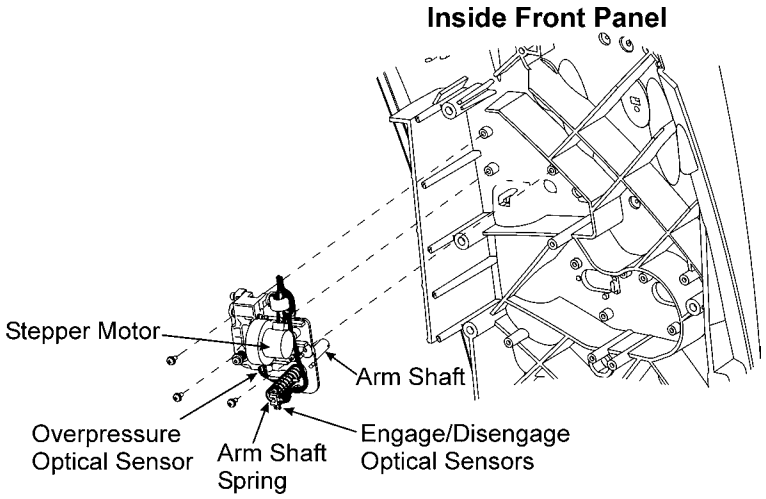

Figure 11-2. Heparin Pump Assembly

11.2.5 Syringe Overpressure Alarm

The heparin pump uses an end-of-stroke (overpressure) infrared optical sensor that monitors the engagement of the rack and pinion which is utilized for the overpressure alarm state. A pin located on the motor mount is positioned between the LED and detector of the optical sensor. This pin will normally occlude the light from the LED into the detector when the gear rack and the motor gears are properly engaged, or when no slide assembly is installed in the Instrument. If this pin is displaced from the optical sensor, it means the gear rack and motor gears have disengaged, pushing the motor mount outward. This is an indication of an overpressure condition and an overpressure alarm will occur within 15 minutes. See Figure 11-3.

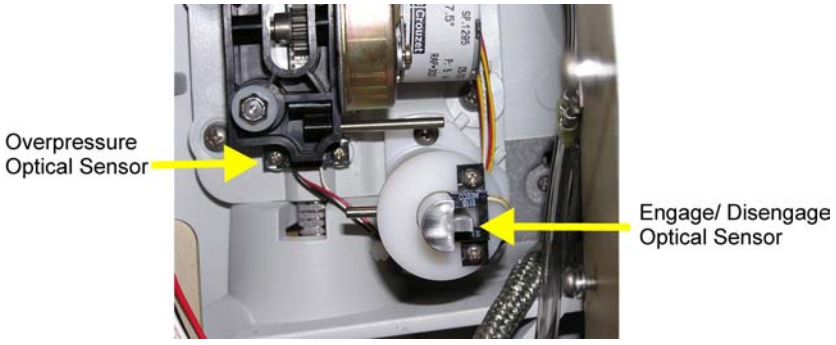

Figure 11-3. Heparin Pump Optical Sensors

11.3 FUNCTIONAL DESCRIPTION

Figure 11-4 is a block diagram describing the heparin delivery system. You may wish to refer to it during the following discussion.

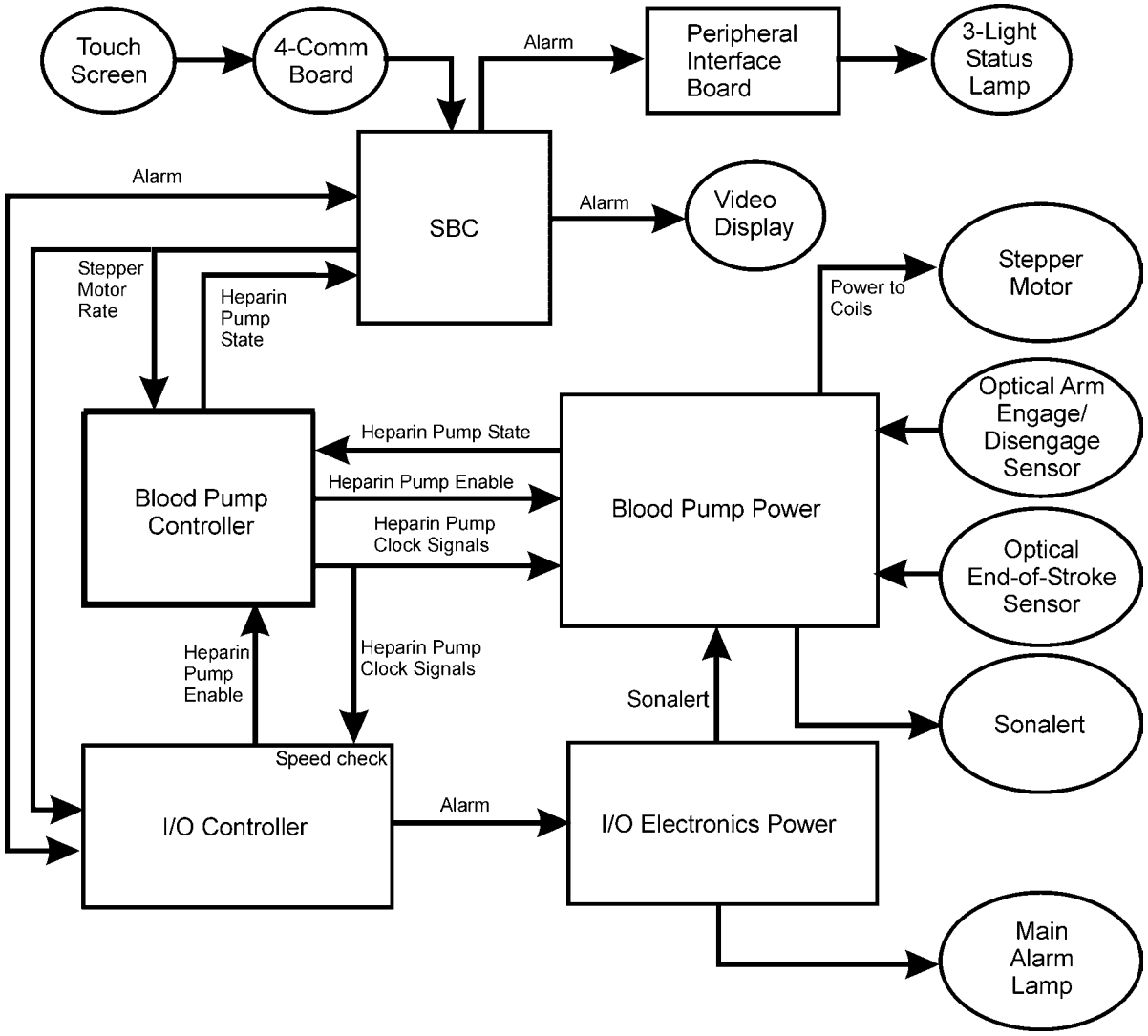

Figure 11-4. Heparin Delivery System Block Diagram

11.3.1 Heparin Pump State

The two optical sensors, end-of-stroke (for the overpressure alarm) and arm engage/disengage, provide information about the state of the heparin pump as explained in Sections 11.2.3 and 11.2.5.

The Blood Pump Controller monitors the state of these sensors via the Blood Pump Power Board and passes the information to the Single Board Computer.

11.3.2 Stepper Motor Drive Control

The heparin pump circuitry on the Blood Pump Power Board drives a stepper motor (see 11.2.4), which controls the rate of injection from the syringe. The stepper motor rotates a pinion mechanism. The pinion moves the rack and the plunger foot moves the heparin syringe plunger the same distance.

To increase the accuracy of the heparin pump during start-up, when the heparin pump is on, the syringe holder arm has just been engaged, and an end-of-stroke is detected, the motor will run at a higher rate for up to 1.7 seconds to engage the gears.

The operator enters a desired heparin rate in milliliters per hour (mL/h) via the front panel touch screen. The Single Board Computer (SBC) displays this rate on the screen, converts it to the appropriate heparin pump motor step rate, and passes the information to the Blood Pump Controller and I/O Controller. The Blood Pump Controller outputs a motor step rate clock signal to the Blood Pump Power Board where the Blood Pump Power Board energizes the appropriate stepper motor coils.

11.3.3 Stepper Motor Driving Monitoring

The motor step rate clock signal from the Blood Pump Controller is also input to the I/O Controller board. The I/O Controller monitors this signal to determine if the heparin motor is operating at the appropriate speed. If it determines that an overspeed condition exists, it disables the heparin motor via an enable line that goes through a hardware line on the Blood Pump Controller Board to the Blood Pump Power Board. The alarm signal is set to 11% over the desired rate. The alarm signal is also sent to the SBC to cancel the stepper motor rate signal and create an audio and visual alarm.

11.3.4 Bolus Infusion Control

Via the Touch Screen, the operator infuses a 0.3 to 5.0 mL bolus of heparin into the extracorporeal bloodline with a 20 or 30 mL capacity syringe (0.3 to 4.0 mL bolus for a 10 mL capacity syringe). The SBC sends to the Blood Pump Controller and I/O Controller boards the number of motor steps to be taken at the bolus rate. During bolus infusion the I/O Controller board will cause an overspeed alarm to occur if an excessive number of high-speed steps occur.

11.4 TROUBLESHOOTING

11.4.1 Overspeed Alarm

Refer to Figure 11-4. To ensure that the heparin pump does not exceed its set speed, the I/O Controller board software monitors a motor step rate clock (logic) signal from the Blood Pump Controller board that is equivalent to 1/4th the heparin pump step rate. In the event that a heparin pump overspeed occurs, the I/O Controller board disables the heparin pump via a hardware line that goes to the Blood Pump Power Board and notifies the SBC of the alarm.

To determine if the heparin pump is running at the correct speed, the time it takes for ten clock signals to occur is measured and compared against a minimum time period that is set by the SBC. If the measured period is less than the SBC set limit, an overspeed alarm occurs. The SBC is notified of the alarm and the heparin pump is disabled via the hardware line to the Blood Pump Power Board.

When the heparin pump rate changes, the SBC resets the minimum time period, and the I/O Controller board waits for the first clock signal to restart the timer (this first clock is not counted as one of the ten). In this way, the alarm logic is resynchronized with the heparin pump stepper motor.

The I/O Controller board also monitors the total amount of heparin delivered in the high-speed bolus mode. When it receives clock signals at a rate faster than a predetermined speed, it assumes the pump is operating in the high-speed mode. It has a high-speed counter, which is set by the SBC. If more high-speed counts occur than are in the counter, a high-speed alarm occurs. The SBC is notified of the high-speed alarm and the heparin pump is disabled via the hardware line to the Blood Pump Power Board.

11.4.2 Arm Engage/Disengage Failure

The signal from the “arm engaged/disengaged” optical sensor can be monitored on R46 on the Blood Pump Power Board. This sensor is also plugged into PF23 in the Blood Pump Power Board. This signal will be low when the heparin pump is disengaged.

11.4.3 Overpressure Alarm

The end-of-stroke sensor will cause an alarm if the heparin rack can not deliver the specified amount due to occlusion and/or an empty syringe. The signal can be monitored on R47 on the Blood Pump Power Board. This signal will be high and go low when an

alarm is generated. The optical sensor also plugs into PF23 on the Blood Pump Power Board.

11.4.4 Coil Resistance

The approximate resistance on the coils of the heparin motor can be checked at PF23:

Pins	Ohms
1-3	70
3-2	70
1-2	130

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12. PRESSURE MONITORING

The purpose of the Pressure Monitoring System is

- to control, measure, and monitor the pressure in the drip chambers of the extracorporeal circuit
- to measure dialysate pressure
- to calculate the transmembrane pressure (TMP).

The optional Noninvasive Blood Pressure Monitor (NIBP) tracks the patient's blood pressure using separate hardware. Refer to Section 12.3 for more information on this optional feature.

12.1 EXTRACORPOREAL CIRCUIT

There are two configurations for the extracorporeal circuit pressure monitoring:

- Arterial and Venous
- Arterial, Venous, and optional Single Needle (SND)

Extracorporeal circuit measurement and monitoring is accomplished by the following hardware:

- Luer connectors
- Internal pressure transducer protectors
- Electromagnetic valves
- Pressure transducers
- Vent filter (transducer protector)
- Peristaltic pump and DC motor
- Blood Pump Controller and Power Boards
- Associated tubing

The luer connectors, transducer protectors, electromagnetic valves, and pressure transducers are identical for each of the subsystems (arterial, venous, and optional SND).

See Figures 12-1, 12-2, and 12-3 for the location of this hardware in the Instrument.

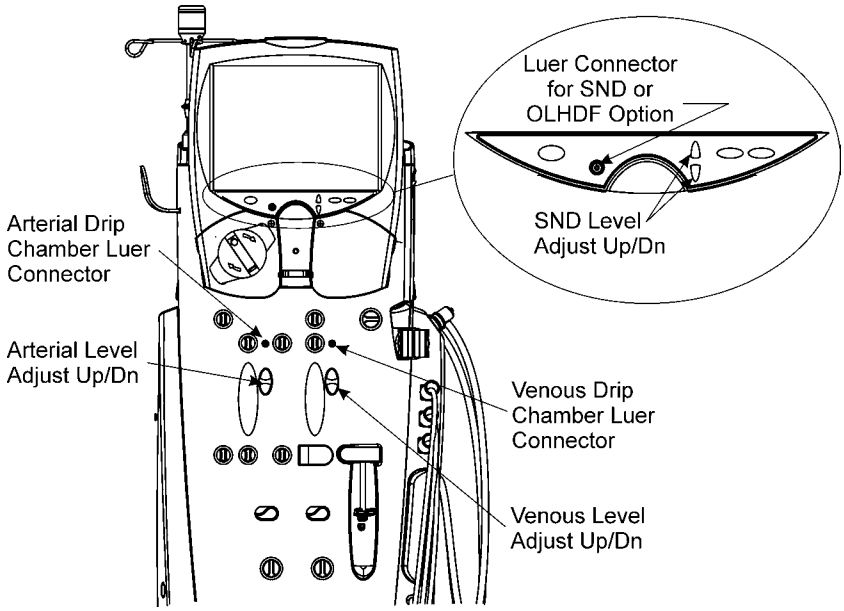

Figure 12-1. External Connections and Controls

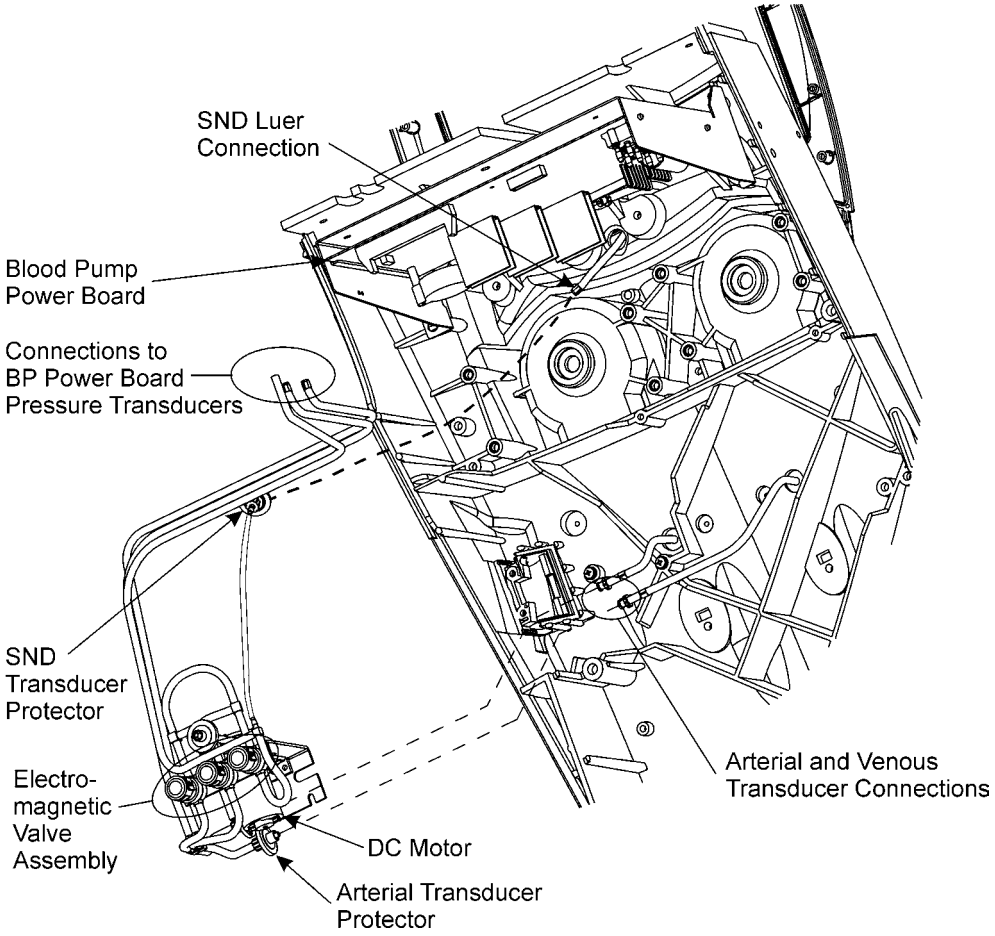

Figure 12-2. Extracorporeal Circuit Pressure Monitoring System

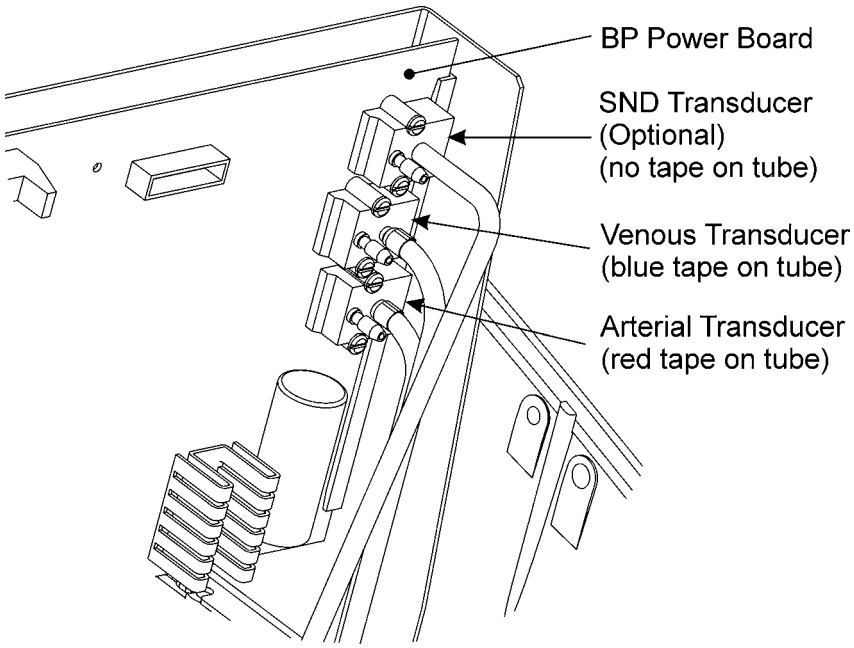

Figure 12-3. Pressure Transducers

12.1.1 Monitoring

The arterial and venous monitors (pressure readings on the video display) indicate pressures in the extracorporeal arterial and venous drip chambers. Whenever the pressure indicator goes outside of the alarm limit window for more than the delay period (0 to 6 seconds, see Section 17.3.2.15) set by the technician, the Instrument goes into alarm.

During an arterial or venous blood pressure alarm, the following events will occur:

- the main alarm lamp flashes
- the appropriate alarm indicator flashes on the screen
- the 3-light status lamp flashes
- the audio alarm sounds
- the blood pump stops
- the venous line clamp occludes the venous blood line
- the UF rate automatically goes to 0 L/h
- the elapsed time stops if the Instrument is in the Dialyze Mode.

12.1.2 Measurement

Extracorporeal circuit pressure measurements include the arterial and venous pressures. There is also an identical circuit for the expansion chamber pressure used with the double pump single needle device on the Blood Pump Power Board. All pressure measurement systems include identical hardware. The following block diagram describes the pressure measuring system.

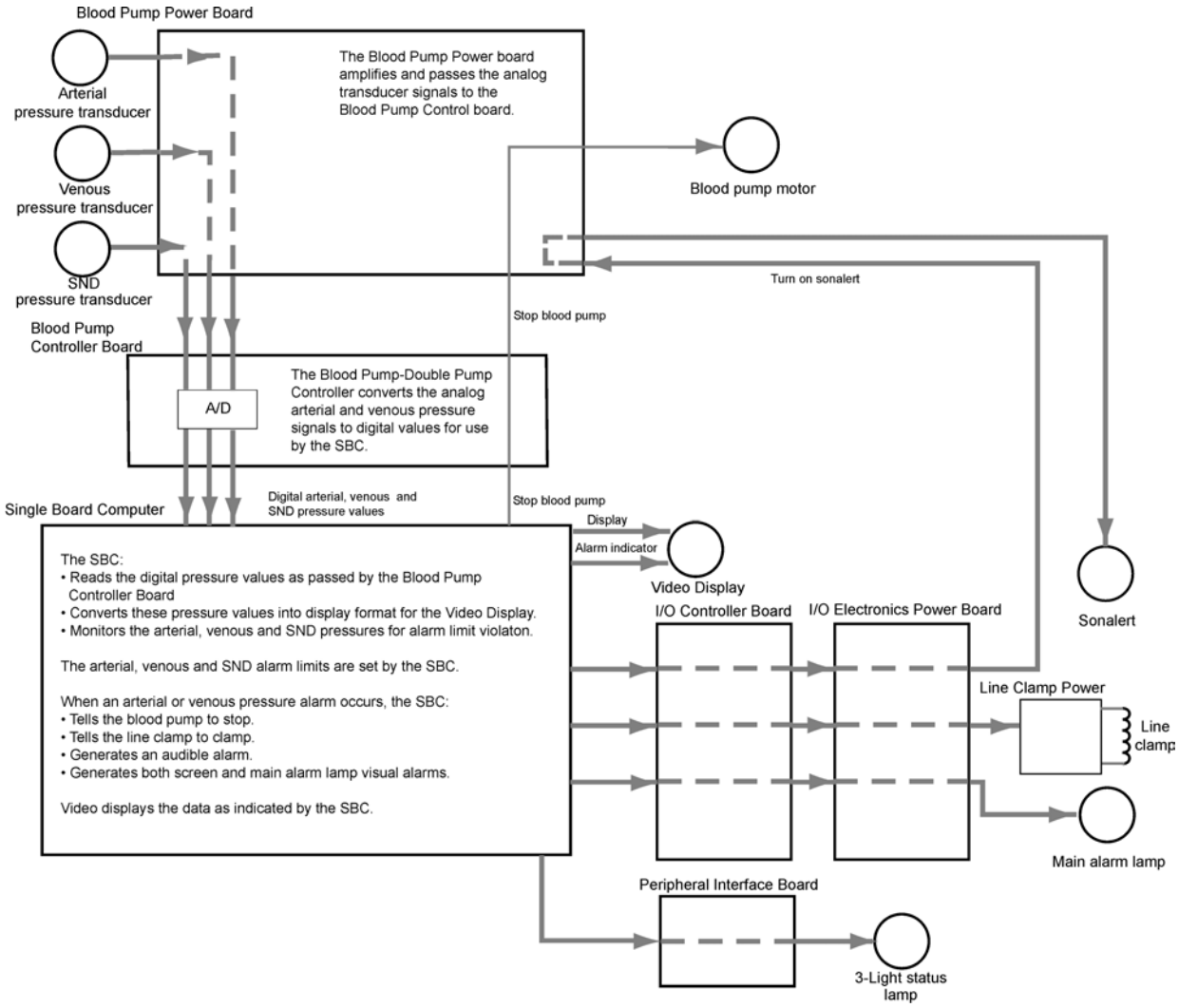

Figure 12-4. Arterial, Venous, and SND Pressure Block Diagram

Blood Pump Power Board

Each pressure is sensed by a gauge pressure-sensing transducer mounted to the Blood Pump Power Board. The purpose of a pressure transducer is to convert a positive or negative pressure into a corresponding electrical signal. Each transducer is connected to a differential amplifier designed to provide a

measurement range from –300 to +600 mmHg. The BP Controller Board uses the signals from these amplifiers.

Blood Pump Controller Board

The output of each amplifier on the BP Power Board drives an A/D input channel on the Blood Pump Controller board, at which point it is converted to a digital value. The calibration of each pressure input is handled entirely in software, requiring that the design of each amplifier guarantee that its output remain within the A/D input range of 0 to +5 V over the input pressure range and over all component tolerances.

The Blood Pump-Double Pump Controller Board provides the digital pressure value to the Single Board Computer (SBC).

Single Board Computer

The SBC compares the pressure value with the alarm limits. On detection of a pressure alarm condition lasting longer than the service technician-set alarm delay (see Section 17.3.2.15), the SBC creates an audio and visual alarm, commands the Blood Pump Controller to stop the blood pump, and commands the I/O Controller to clamp the venous line clamp. When the venous line clamp is clamped, the I/O Controller also shuts off the blood pump.

12.1.3 Drip Chamber Level Adjust

The Drip Chamber Level Adjust System allows the operator to change the blood level in the arterial and venous drip chambers as well as the optional SND Expansion Chamber. It also allows the operator to purge the single-use external ultrafilter used in an Instrument with the optional OLHDF feature.

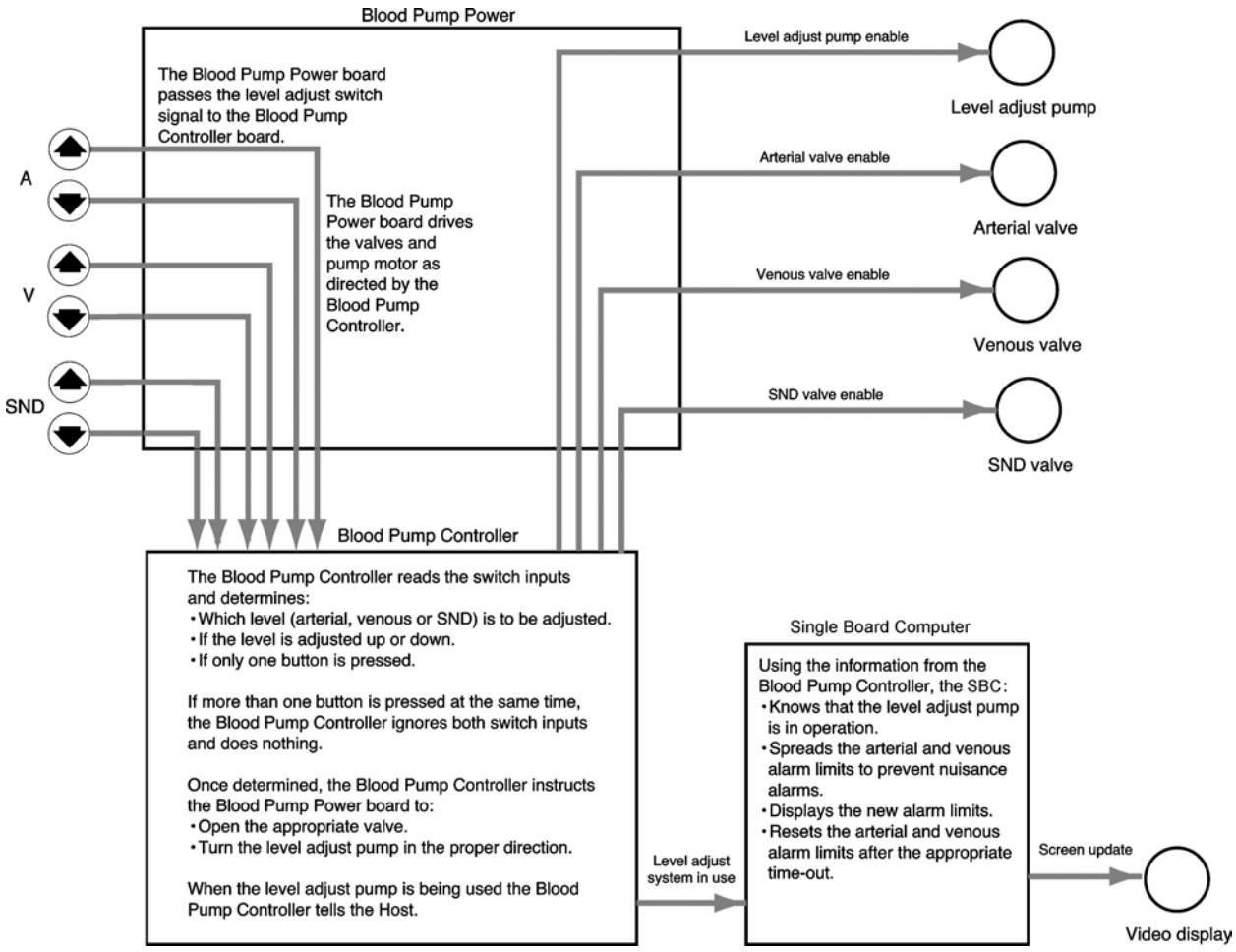

Figure 12-5. Arterial Drip, Venous Drip, and SND Expansion Chamber Level Adjust

A level adjust up and level adjust down button exists for each drip chamber. The Blood Pump Controller Board monitors the button positions. When the venous level adjust button is pressed, a valve opens up a peristaltic pump to the venous drip chamber. Power is supplied to the motor, rotating the pump head of the peristaltic pump. The peristaltic pump applies a vacuum or a positive pressure to the drip chamber. The software logic accepts only one button press at a time. If two buttons are pressed simultaneously,

both are ignored. If a button is held longer than approximately 5 seconds, it times out.

The motor drive circuitry is located on the Blood Pump Power board. The motor may be driven in the forward or reverse direction. A direction signal from the Blood Pump Controller board, along with a pulse width modulated motor rate signal, controls two bipolar half-bridge motor drivers. Both half-bridge motor drivers receive the same motor rate signal, while the motor direction signal is high at one and low at the other to determine the direction the motor runs. The half bridge drivers provide a 24 V pulse width modulated drive voltage of approximately 30 kHz to the motor.

WARNING

Handle used blood lines, dialyzers, transducer protectors, and blood contaminated components as potentially biohazardous waste. Refer to the clinic's procedures for the disposition of these items.

Connected to the venous and arterial monitors is a small motor-operated peristaltic pump (SND option is not shown in Figures 12-4 and 12-5). This pump is used to raise or lower the level of blood in the extracorporeal blood line drip chambers.

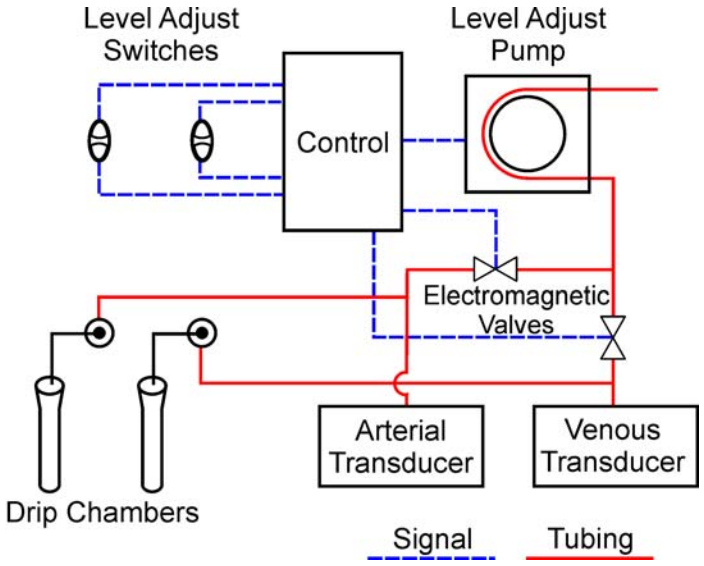

Figure 12-6. Pressure Monitoring and Level Adjust Block Diagram

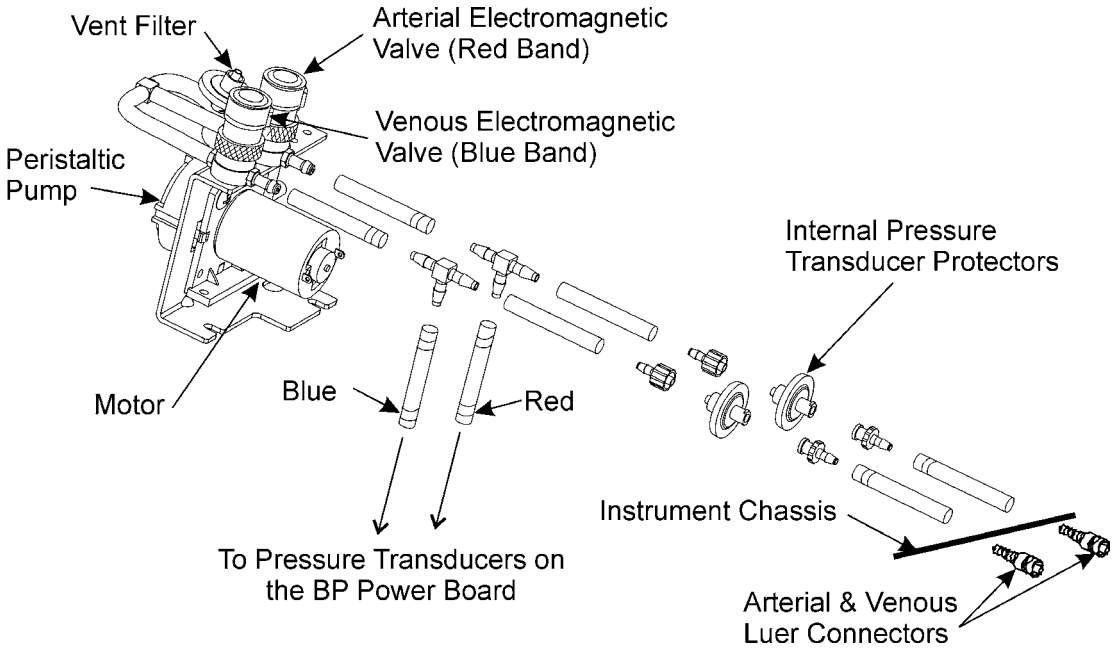

Figure 12-7. Pressure Monitoring/Level Adjust Hardware (standard)

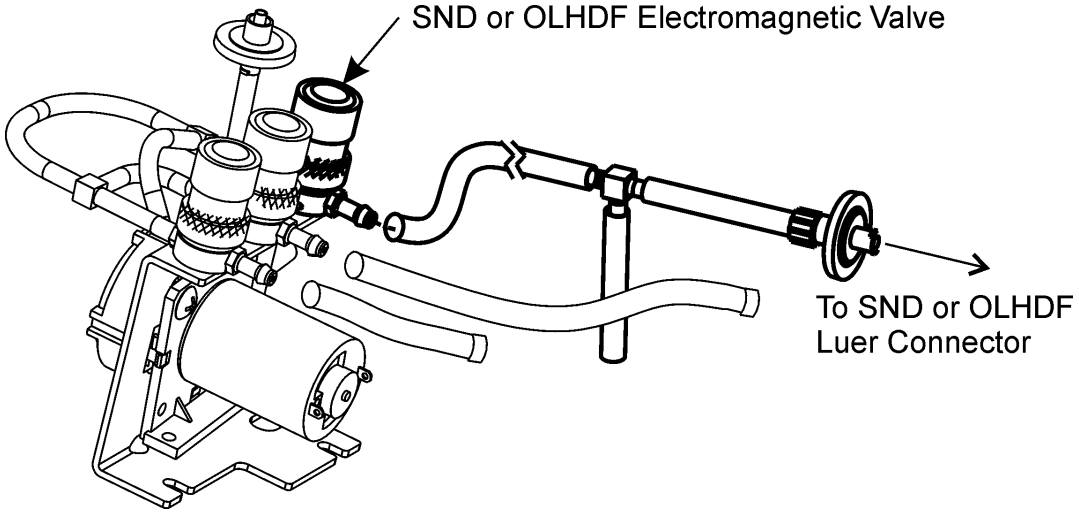

Figure 12-8. Pressure Monitoring and Level Adjust Hardware with SND or OLHDF Options

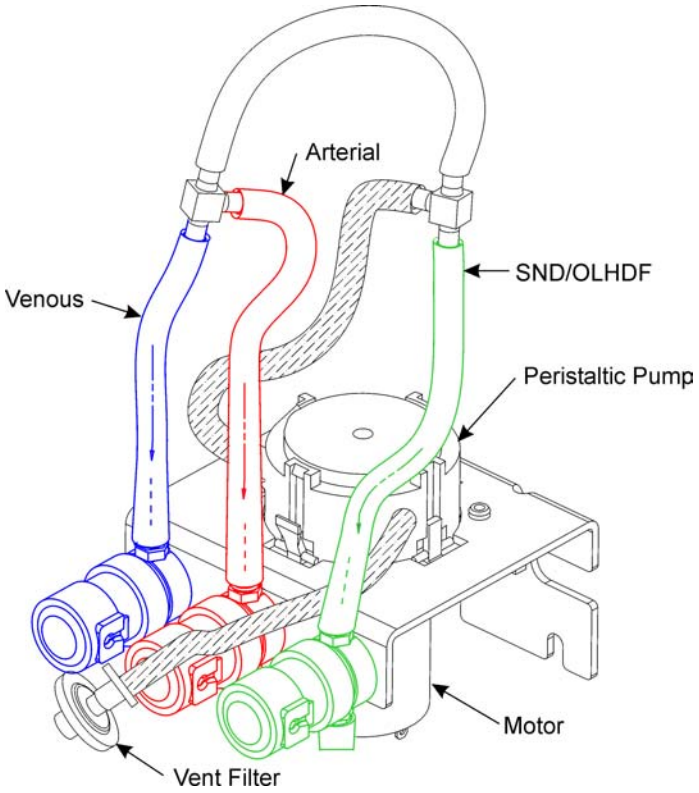

Figure 12-9. Detail of Level Adjust Tubing with SND or OLHDF Options

During the Standby, Rinse, and Prime Modes (and Dialyze Mode when the blood pump is manually turned off), the arterial pressure alarm limits are wide open (–300 to +600 mmHg). The venous pressure alarm limits are set ±200 mmHg around the indicated venous pressure at the beginning of the Rinse Mode or 10 seconds after the blood pump rate is changed.

During Prime Mode (with the extracorporeal alarms armed) and Dialyze Mode the Instrument will perform as follows:

- Blood Pump (BP) is started
- BP rate display changed
- Level adjust buttons pushed
- RESET button touched.

The arterial and venous pressure alarm limits open to ±200 mmHg around the appropriate indicated pressure. After 10 seconds, the arterial and venous alarm limits close to ±50 mmHg around the respective pressure with the low venous alarm limit being no less than +10 mmHg.

12.2 TRANSMEMBRANE PRESSURE

Transmembrane pressure is the hydrostatic pressure difference inside the dialyzer across the membrane from the blood side to the dialysate side.

"Venous pressure minus dialysate pressure" is the approximation used to determine the TMP that is displayed on the Instrument screen. Refer to Figure 12-10 for a TMP block diagram and to Section 4.2.13 for the location of the dialysate pressure transducer.

During the Standby, Rinse and Prime Modes, the TMP alarm limits are ±290 mmHg (within the range from technician set low alarm limit (Section 17.3.1.11) to +500 mmHg) for approximately 100 seconds after the Blood Pump (BP) is turned on, BP or UF rate is changed, the level adjust pump is operated, or the RESET button is touched.

When the Dialyze Mode is started, the blood pump is started, the blood pump is manually turned off, the blood pump rate changed, or the UF rate is changed, the TMP alarm limits open to a 580 mmHg span within the range of the service technician-set lower alarm limit to +500 mmHg for approximately 100 seconds. After the 100 seconds, the alarm limits automatically set to ±35 mmHg of the indicated TMP (repositioning the alarm window as required). The TMP alarm limits may be manually set to ±35 mmHg of the indicated pressure by touching the SET LIMITS button.

During the Dialyze Mode, when a level adjust button pushed or the RESET button touched, the TMP alarm limits open. After 100 seconds the TMP alarm limits close maintaining the previous alarm window position.

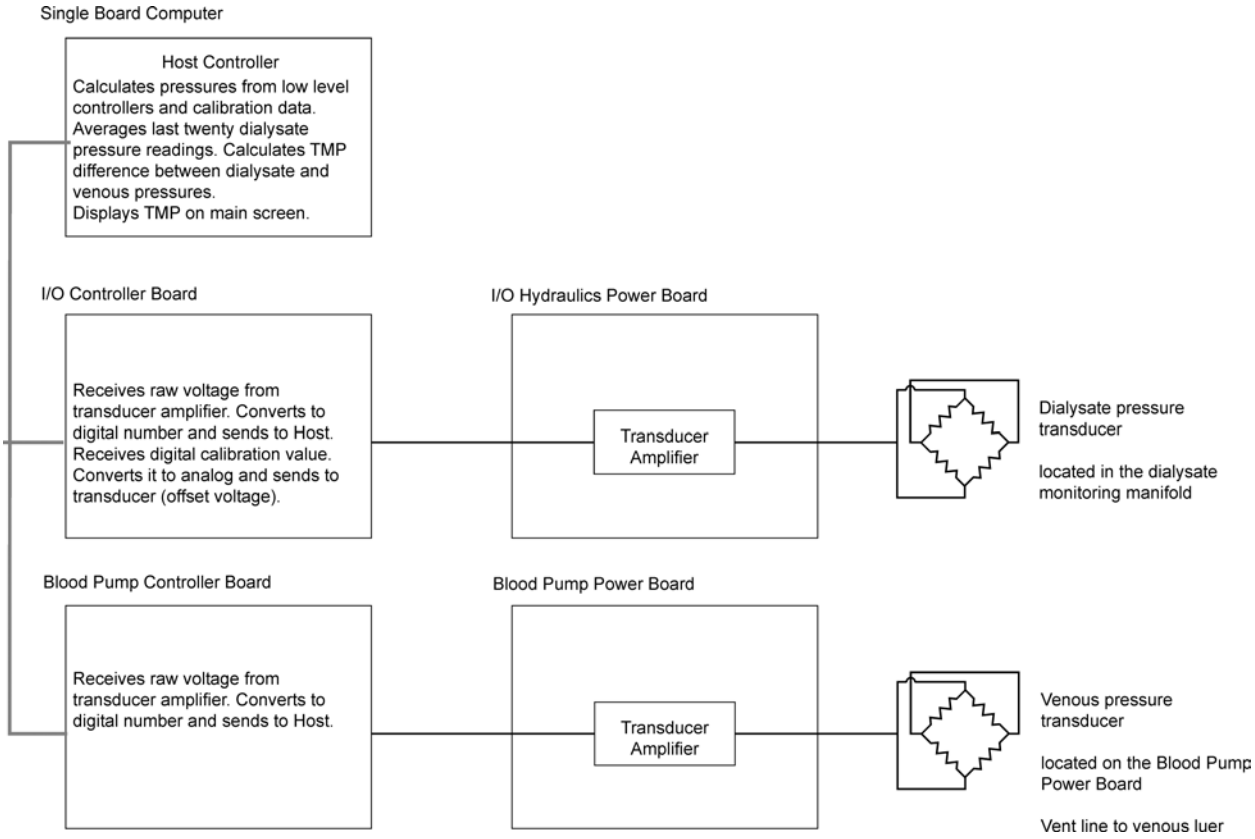

Figure 12-10. TMP Block Diagram

12.3 NIBP OPTION

12.3.1 Overview

The Noninvasive Blood Pressure (NIBP) Monitor communicates with the SBC via the Peripheral Interface board. See Section 5.9 for more information.

The Switching Power Supply provides the +5, +12, -12 VDC power and ground for this module via the Peripheral Interface board. See Section 5.9 for more information.

The NIBP Monitor consists of the following components:

- Cuff, connecting tubing, and holder
- Cuff port
- Blood pressure module

See Sections 2.4.8 and 2.8.1 for a brief description and location of these components.

The optional NIBP Monitor permits the operator to obtain a patient blood pressure history during treatment. The interval between automatic blood pressure readings can be set at 5, 15, 30, 45, or 60 minutes, or OFF. This automatic blood pressure reading schedule may be set and started, changed, or manually turned off by the operator during the Prime and Dialyze Modes. The schedule is automatically turned off at the transition into the Rinse Mode.

At the end of a successful Self Test Mode, the blood pressure history is erased.

If a valid pulse reading is not obtained during a blood pressure reading, **"?"** is displayed for the pulse, but the blood pressure reading is displayed.

The factory-set alarm limits are shown in Table 12-1.

Table 12-1. Pressure Limits

Pressure	Minimum	Maximum
Systolic	100 mmHg	200 mmHg
Diastolic	60 mmHg	200 mmHg

Refer to Section 27.5.1 for the NIBP Monitor specifications.

In the event of a power failure or soft power off of less than approximately 20 minutes, the NIBP Monitor settings and blood pressure history are saved. The pressure cuff will automatically deflate during a power failure or soft power off.

The NIBP Monitor uses the oscillometric method of noninvasive blood pressure measurement. The Monitor measures the systolic, diastolic, and mean blood pressures, and the average heart rate.

The cuff automatically deflates to 165 mmHg during the first blood pressure reading or after a blood pressure error. During the next blood pressure reading after a successful reading, the cuff automatically inflates to the previous systolic pressure plus 30 mmHg. An overpressure switch automatically deflates the cuff at approximately 330 mmHg.

12.3.2 Troubleshooting

When the cuff is inflated to a target pressure (higher than the patient's systolic pressure), the oscillometric NIBP Monitor looks for a pulse, which is detected as small fluctuatoins in the cuff pressure. Since patient movement can also cause small pressure fluctuations, the pulse is "screened" by looking for similar pulses within a range of normal pulse frequencies.

If the monitor is unable to detect a "screened" pulse, a no reading error code is transmitted and displayed on the Arena Instrument screen as **905: No Reading**.

The most common cause of **905: No Reading** errors is movement. This can be corrected by making sure the patient and connecting hose are still during the reading.

Some conditions that cause inconsistent pulses are correctable.

- The cuff *must* be properly sized, properly aligned over the artery, and fit snugly when deflated.
- Loose or thick clothing may cause problems in locating a pulse signal.
- Pressure fluctuations can be transmitted to the monitor from the hose. The hose *must* be unobstructed and free of kinks and tangles.
- Low target cuff pressure and high patient blood pressure can cause errors. If the target pressure is lower than the patient systolic pressure, the monitor may misinterpret pulse fluctuations and return a **905: No Reading** error. A cancelled reading or error condition resets the target cuff inflation pressure to 165 mmHg.
- Patient conditions such as allorhythmic pulse (pulse with a repeating irregularity) and bigeminal pulse (a pulse beat that occurs in pairs), old shunts, and medications may cause

inconsistent pulses and result in a **905: No Reading** error. The NIBP Monitor may not work well with these patients.

Refer to Section 26.39.1, or to the Operator's Manual for additional alarm messages.

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13. BLOOD/SALINE AND AIR DETECTORS

The Blood/Saline and Air Detectors are part of the safety system of the Arena Instrument.

The detection of blood in the venous blood line by the Blood/Saline Detector will automatically activate the Air Detector and prompt the operator to start the treatment. The Air Detector can also be manually activated on the display panel, as well as momentarily reset to clear air from the system. Refer to the Operator's Manual for more information.

The Blood/Saline (optical sensor) Detector and Air (ultrasonic sensor) Detector are two electrically independent components molded into a single module or housing, and both continuously monitor the venous blood line. See Figure 13-1 for location, and Figure 13-2 for the components. If either detector fails, the sensor module must be replaced.

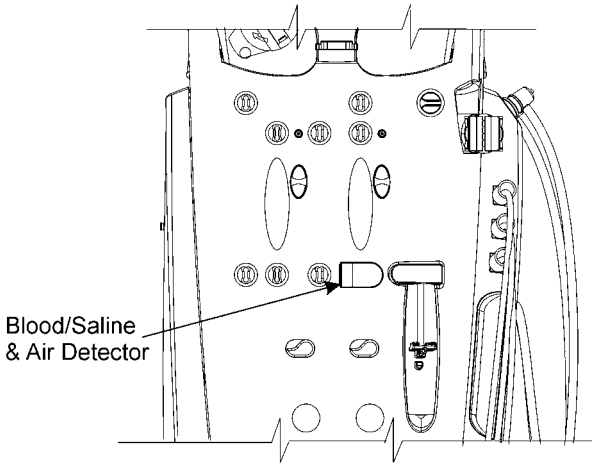

Figure 13-1. Blood/Saline and Air Detector Location

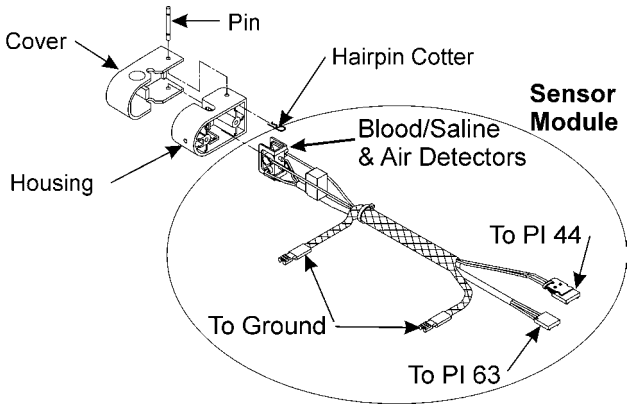

Figure 13-2. Blood-Saline & Air Detector Components

13.1 BLOOD/SALINE DETECTOR

The Blood/Saline Detector is an optical source (LED) of pulsed green light and a phototransistor (detector) that will allow the Instrument to differentiate between the presence of blood and the presence of saline in the venous blood line tubing. This information is used to automatically activate the Air Detector. The Air Detector can also be activated manually.

The Saline/Blood Detector is adjusted to the optical properties of a specific blood tubing during calibration. See Section 18.5.12..

When the detector senses constant light pulses (saline), the extracorporeal alarms may be disarmed in the Prime Mode and the Instrument state may be changed from Dialyze Mode or Standby Mode to Rinse Mode. If the detector senses either no pulse (blood) or constant light (ambient light error), the extracorporeal alarms are armed in the Prime Mode and the change from the Dialyze Mode or Standby Mode to the Rinse Mode is prohibited.

13.2 AIR DETECTOR

13.2.1 Functional Description

The air detector monitors the venous blood line via the I/O Electronics Power Board for the presence of air bubbles by continuously emitting an ultrasonic signal of a known intensity. This ultrasound is monitored by the air detector receptor for any change in characteristics. If the passing blood contains air bubbles equal to or larger than the sensitivity value set in Calibration Mode (see Section 17.3.1.2), the sound reaching the receiver will change enough to cause the Instrument to trigger an alarm.

Warning

The Air Detector housing and blood line must be clean and dry for proper operation. Do not wet or apply other liquids to the Air Detector or external surface of the blood line in the Air Detector. Wetting or the use of other liquids (including ultrasonic gel) could result in reduced air detector sensitivity.

During an air detector alarm the audio alarm sounds, the blood pump stops, the venous line clamp occludes the venous blood line, and the UF rate goes to 0 mL/h. The blood and dialysate pressures will slowly equalize across the dialyzer membrane.

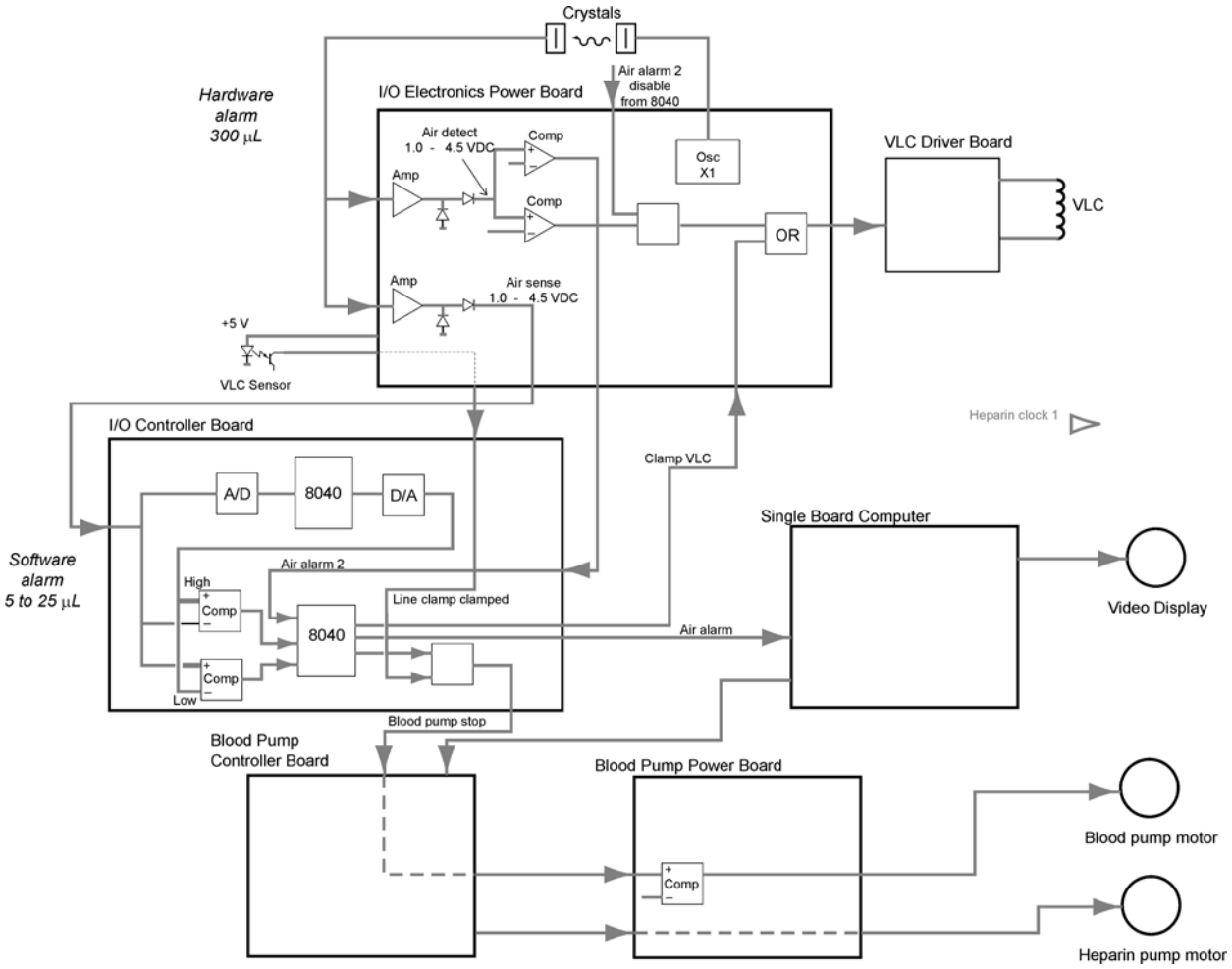

Figure 13-3. Air Detector Block Diagram

The air detector assembly utilizes a set of 2 MHz piezo crystals. One crystal functions as an ultrasonic transmitter and the second crystal functions as a receiver. The emitter and receiver are housed in identical assemblies. The emitter is driven by a 2 MHz square wave that is derived from a crystal oscillator (X1 and related circuitry) located on the I/O Electronics Power Board. When there is fluid in the blood line between the crystal assemblies, the 2 MHz signal is coupled to the receiver assembly. The return signal from the receiver assembly is amplified (U9 and U10) and rectified by two independent circuits also located on the I/O Electronics Power Board. The resulting signal is a DC signal of 1.0 to 4.5 VDC. These DC output levels are monitored using two different methods, software and hardware, each generating a specific alarm. See Sections 13.2.1.1 and 13.2.1.2.

13.2.1.1 Software Alarm Detection (Primary Alarm)

One output is fed from the I/O Electronics Power Board to an A-to-D converter and read by the I/O Controller Board. This value is

averaged over a 400 millisecond time period and reduced by multiplying it by 15/16 and subtracting 50 mV (for noise immunity). This new value is then converted back to an analog level to be used as an alarm limit. This software-generated limit is compared to the rectified DC signal from the detector. The output state of this comparator is monitored by the I/O Controller Board. The voltage from this comparator is sampled every 0.96 ms. When the unaveraged signal falls below the software-generated limit a counter is incremented by 16. The counter limit is set in customizing. When the counter reaches the count limit, an alarm occurs. If the voltage is above the software-generated limit, the counter is decreased by one. The lower limit of the counter is zero. This allows many small bubbles equivalent to a large bubble to be detected. Sensitivity of the software alarm can be calibrated according to Section 17.3.1.2.

13.2.1.2 Hardware Alarm Detection (Secondary Alarm)

The hardware alarm is redundant to the software-generated alarm. This alarm uses two comparators (U7A & U7B) on the I/O Electronics Power Board. One comparator looks for a minimum DC level from the rectified detector signal. The second comparator is AC-coupled to react to a large air bubble in the tubing. Sensitivity of this detector is approximately 300 microliter air bubble. Both comparator outputs are ORed (U4B& U4C) together so that either comparator will generate an alarm.

The hardware alarm provides a signal to the SBC, and the following occur:

- the air alarm information is displayed on the video display
- the main alarm lamp and 3-Light Status lamp flash
- an audio alarm is generated.

The alarm sends a signal to the I/O Controller Board which provides a hardware line to shut off the blood pump. It also causes the input on the line clamp driver board to go LOW so the venous line clamp driver is de-energized, closing the clamp and sealing off the venous blood line.

13.2.2 Air Detector Tests

There are two tests that can be performed on the Air Detector:

- Voltage
- Bubble

Testing the Air Detector is done using sections of the venous blood tubing used by the clinic. This tubing must be within the specifications listed in Section 27.4.4.

The voltage test verifies that the sensitivity of the Air Detector is adequate when using a specific blood line. This test should be performed every time the clinic changes the type of the blood line used, and also during installation, annual preventive maintenance, and Air Detector and SRAM replacement. It may be necessary to add an attenuator to prevent the saturation of the Air Detector. Refer to Section 19.10.1 for a detailed description of this test.

The Bubble Test is optional. It visually verifies the detection of a bubble size as specified in Section 27.4.2. Refer to Section 19.10.2 for a detailed description of this optional test.


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14. BLOOD LEAK DETECTOR

14.1 OVERVIEW

The Blood Leak Detector (BLD) is an optical device used to detect an internal blood leak from the dialyzer into the fluid path. Depending on the circumstances, an external blood leak into the atmosphere would generally cause an extracorporeal alarm. Refer to Section 26, Alarms, and the Operator's Manual for more information on the extracorporeal alarms.

There is a possible delay in detecting an internal blood leak when flow through the dialyzer circuit is at a minimum, such as during manual bypass and sequential ultrafiltration.

The BLD sensitivity can be selected by a trained technician at any of three different levels, independently of the dialysate flow rate. Upon selection of the sensitivity, the Instrument will automatically perform calibration of the BLD. Refer to Section 18.5.11 for more information.

The BLD is accessible for cleaning purposes from the back of the Instrument without having to open any doors. See Figure 14-1.

The purpose of the BLD Drain Line is to evacuate the fluid from the BLD before removing the BLD cover when cleaning the BLD.

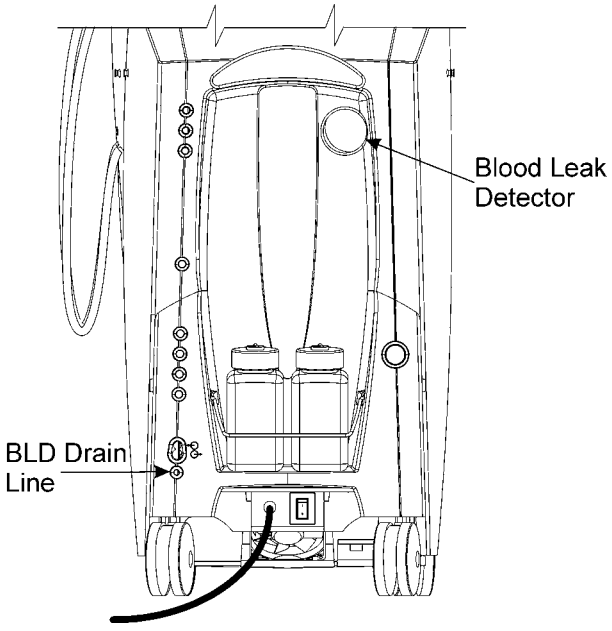

Figure 14-1. BLD and BLD Drain Line Location

14.2 PHYSICAL DESCRIPTION

The BLD assembly consists of a harness with a high efficiency green LED and a photocell, and a housing with a cover. Spent dialysate passes through this assembly allowing the BLD to detect blood in this fluid.

See Figure 14-2 for the location of the BLD in the back of the hydraulics module, and Figure 14-3 for an exploded view of this detector.

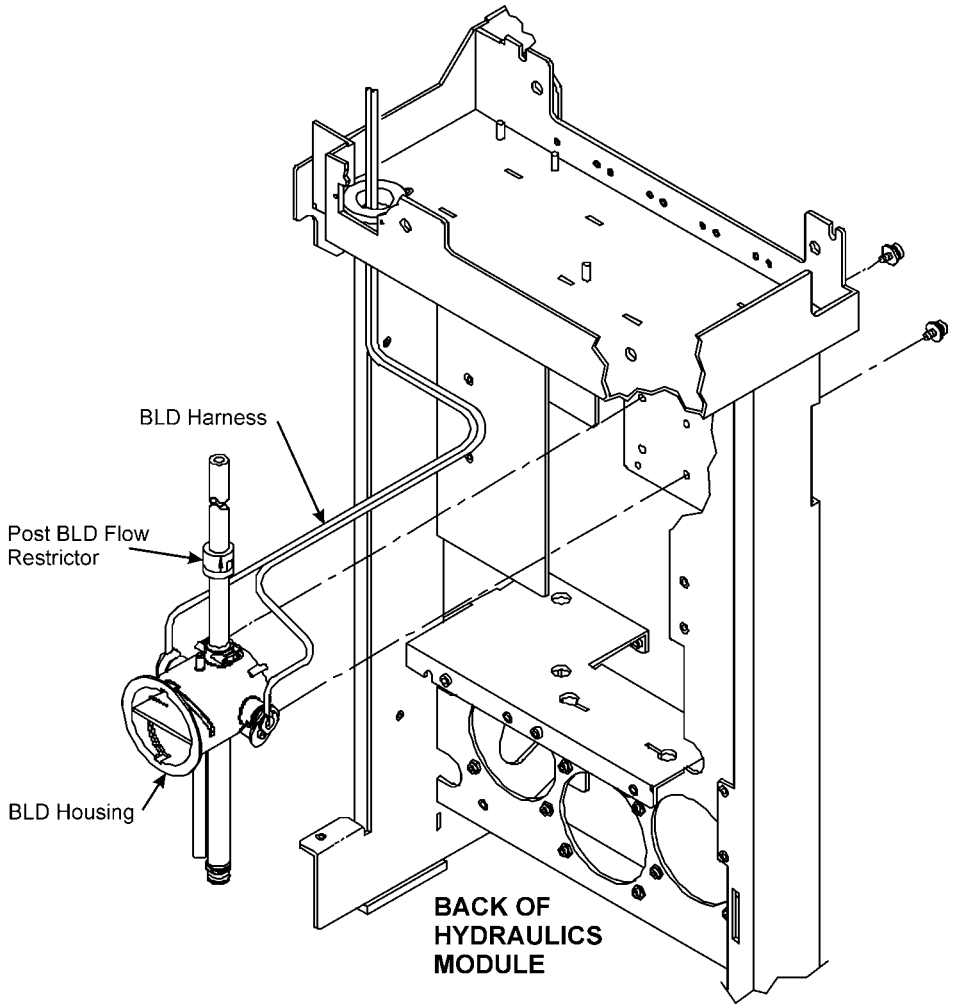

Figure 14-2. BLD Location Inside the Instrument

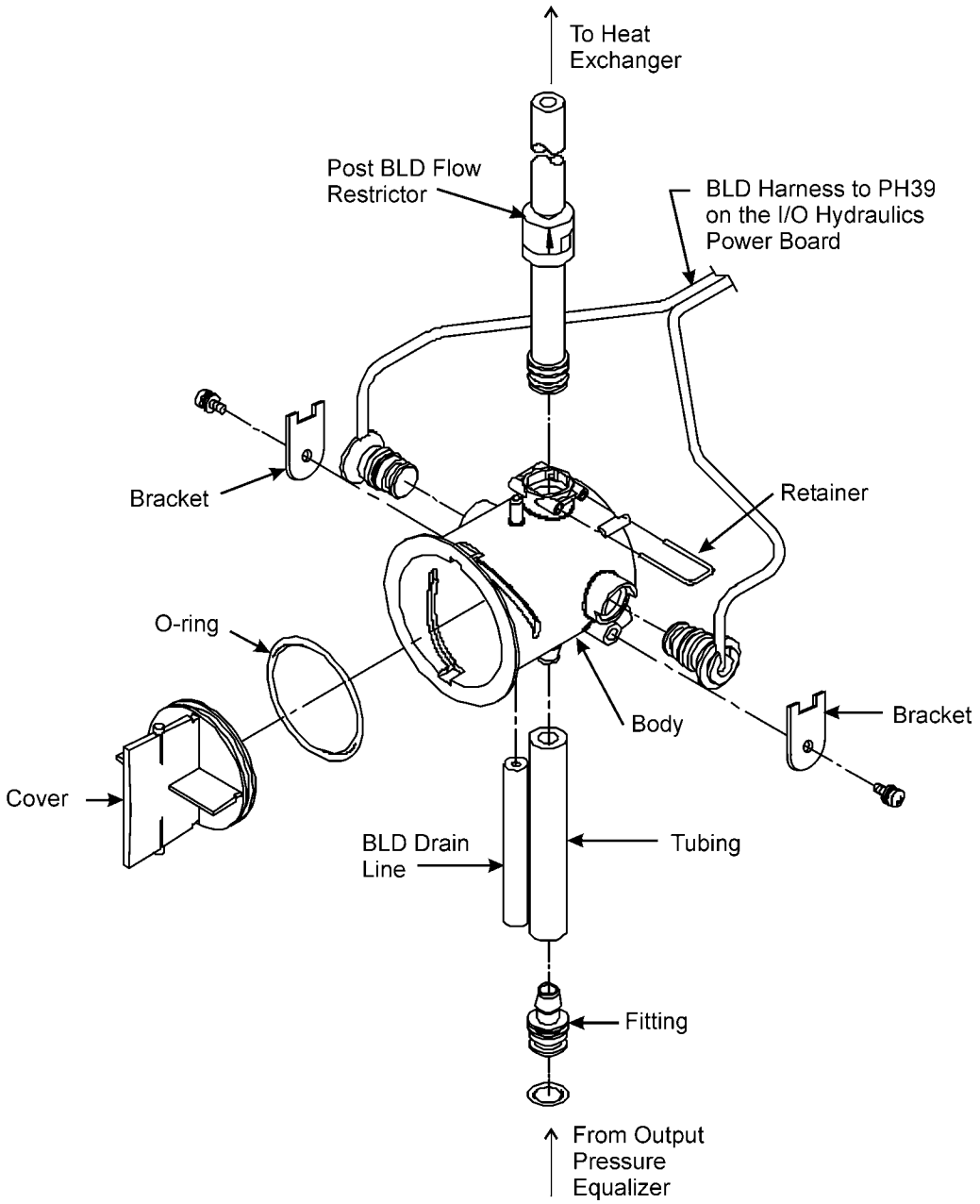

Figure 14-3. BLD Exploded View Including Flow Restrictor

The BLD can be easily cleaned without opening the Instrument; however, the Instrument must be turned off. The BLD housing has a quarter-turn cover that allows the technician to reach the lens of the LED and photodiode from the outside and clean them, thereby preventing nuisance blood leak alarms.

14.3 FUNCTIONAL DESCRIPTION

The Instrument constantly monitors the photocell signal. If blood leaks through the dialyzer membrane, the blood passing between the LED and photocell in the BLD will absorb a portion of the light from the LED, preventing it from reaching the photocell. This change in the amount being received by the photocell will cause the Instrument to trigger a blood leak alarm stopping the blood pump, clamping the venous line, and warning the operator. Bubbles in the BLD could cause the same response creating false alarms.

Both the LED and the photocell connect to the I/O Hydraulic Power board. The LED is connected to a voltage-to-current converter on the I/O Hydraulic Power board. The input to this circuitry comes from the I/O Controller board. The photocell is tied to the +5 V reference supply through a 750 kΩ resistor. This provides a voltage divider which is monitored on the I/O Controller Board.

The current through the LED is adjustable and controlled via a Digital-to-Analog output from the I/O Controller board. The light intensity of the LED is adjusted to illuminate the photocell to a point where its resistance is below the alarm threshold. During a blood leak, the presence of blood in the housing attenuates the light striking the photocell, which causes an increase in both the photocell resistance and voltage. The increase in voltage (monitored by the microcontroller on the I/O Controller board) results in a blood leak alarm.

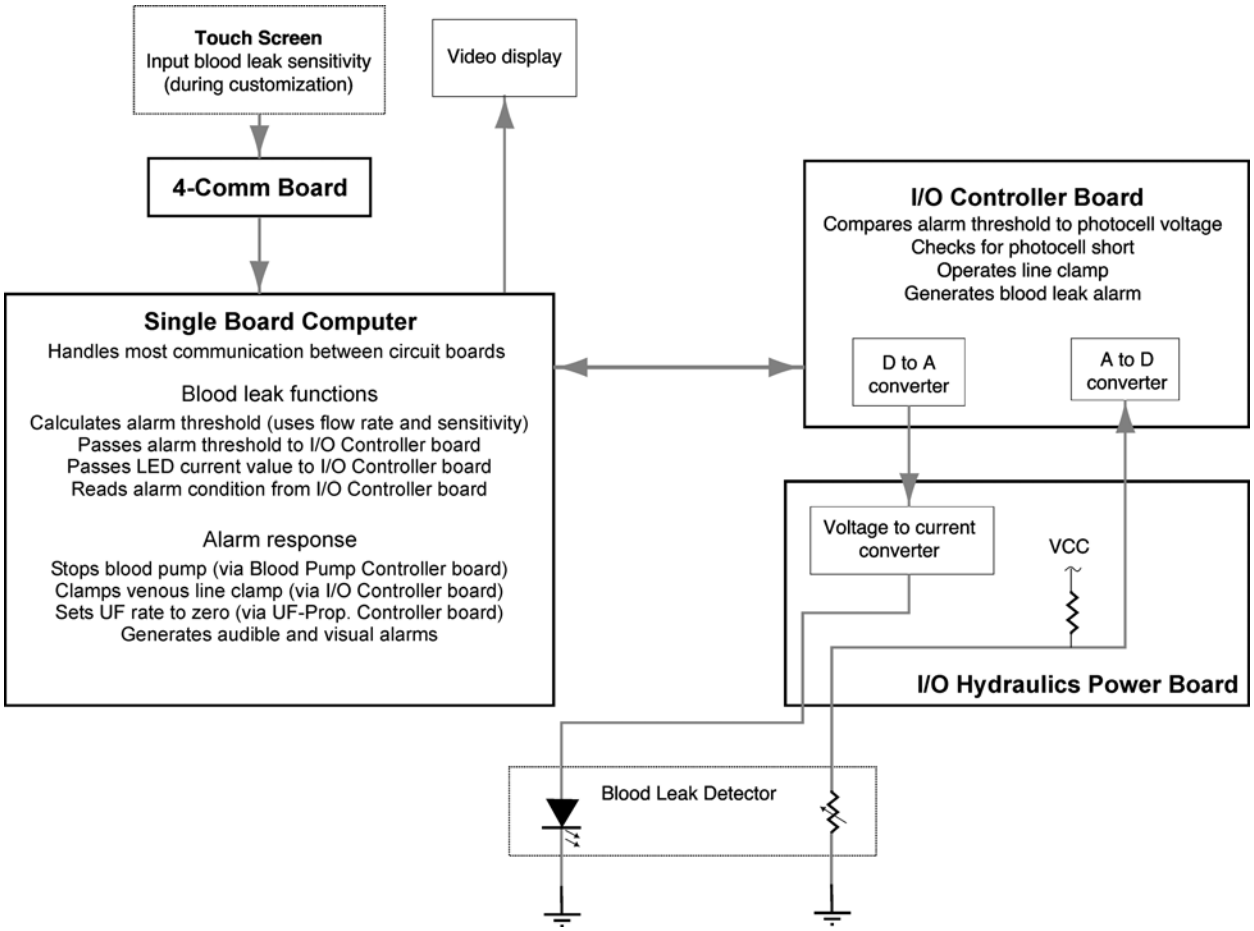

Figure 14-4. Blood Leak Detector Block Diagram

Blood Leak Detector Calibration

The calibration of the BLD is performed automatically at a flow rate of 500 mL/min when the technician selects the sensitivity of the BLD (see Section 18.5.11). This sensitivity is selected in terms of mL/min blood leak rate. The I/O Controller varies the LED light intensity via the I/O Hydraulic Power Board until the signal from the photocell measures about 2 VDC. The LED voltage value is stored in the SRAM.

The actual BLD alarm threshold depends on two variables, the BLD sensitivity selected during customization and the actual dialysate flow rate used during each treatment.

14.4 POST BLOOD LEAK DETECTOR FLOW RESTRICTOR

Refer to Figure 14-3 for the physical location, and to Figure 14-5 for the location in the fluid path.

This is a flow restrictor or false check valve. A flow restrictor is externally the same as a true check valve. The difference is inside the valve. A flow restrictor has a hole in the center of the valve which allows a free flow in the direction indicated by the arrow on the body of the restrictor, and a flow restriction in the opposite direction.

This flow restrictor does not in any way affect the operation of the BLD; however, it is covered in this section due to the close connection to the BLD.

This flow restriction ensures that there is always positive pressure on one side of the output pressure equalizer. Notice that Instruments with the OLHDF option will have a flow restrictor with a 5 (PSI) label on the body, and should be replaced by the same kind of flow restrictor. If there is no number on the body, then it is a 3 PSI valve (used for non-OLHDF instruments).

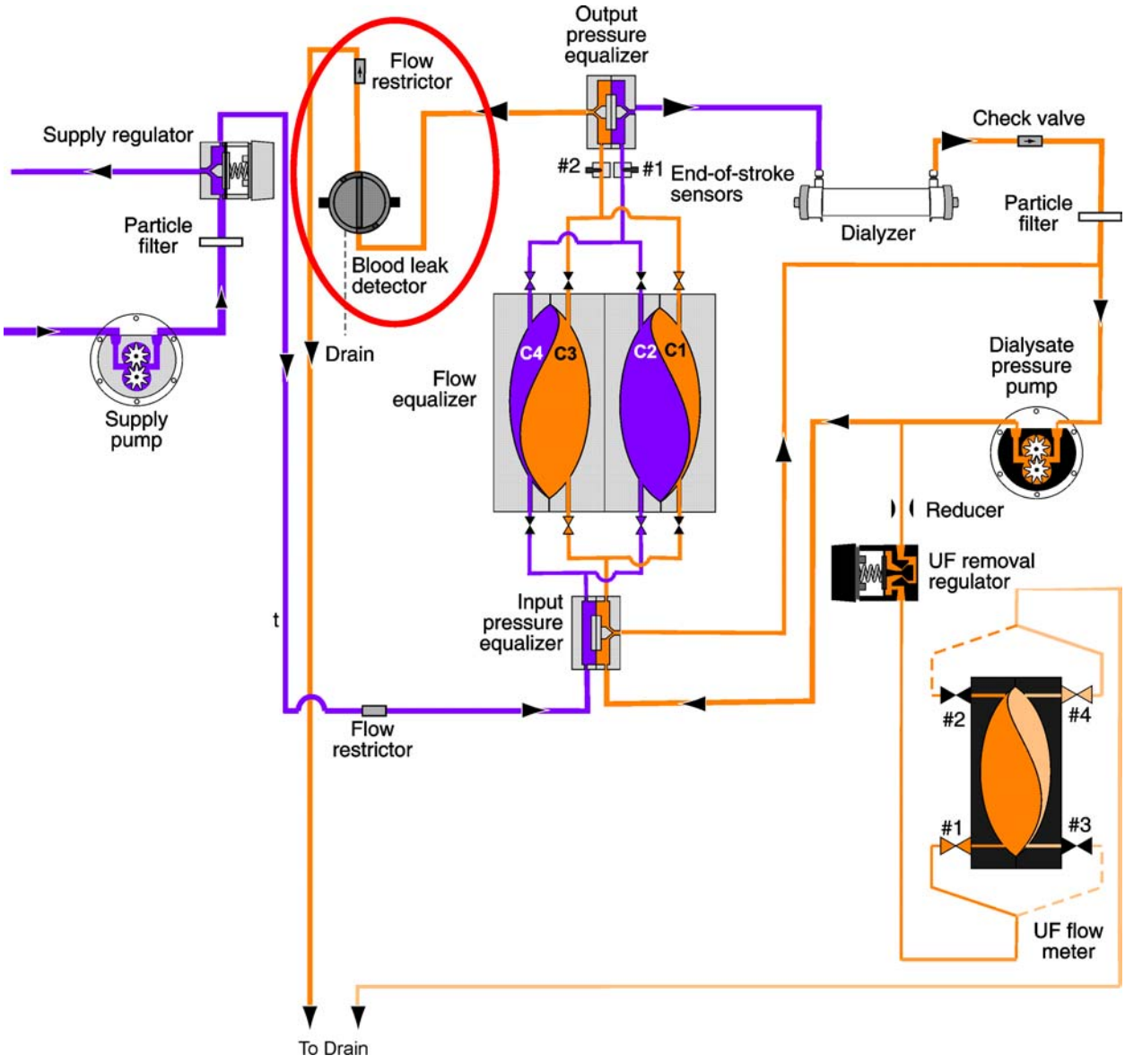

Figure 14-5. Blood Leak Detector and Flow Restrictor

14.5 TROUBLESHOOTING

False BLD Alarms

False BLD alarms may be triggered by bubbles in the BLD path because the bubbles scatter the light as real blood would. Make sure there are no leaks in the hydraulic system and pressures are within range. Also, make sure the LED and photocell lens are clean.

UF Sytem 2 Error

This alarm may be caused by the post BLD flow restrictor. The flow restrictor could eventually be damaged by the sodium hypochlorite and Amuchina solutions used to disinfect the Instrument. In this case, the O-ring inside the flow restrictor could swell dislodging the O-ring from its seat and causing the valve to fail. Make sure to use the appropriate 3 or 5 PSI flow restrictor. Refer to Section 14.4.

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15. PATIENT DATA CARD SYSTEM

15.1 GENERAL

The Patient Data Card system provides a convenient means for initializing Instrument settings for a particular patient or general therapy.

This system allows the transfer of patient information and treatment data from Renal Soft software to the Instrument.

The Patient Data Card (PDC) system (Figure 15-1) consists of the PDC Programmer, Patient Data Card, PDC Reader, and Peripheral Interface Board.

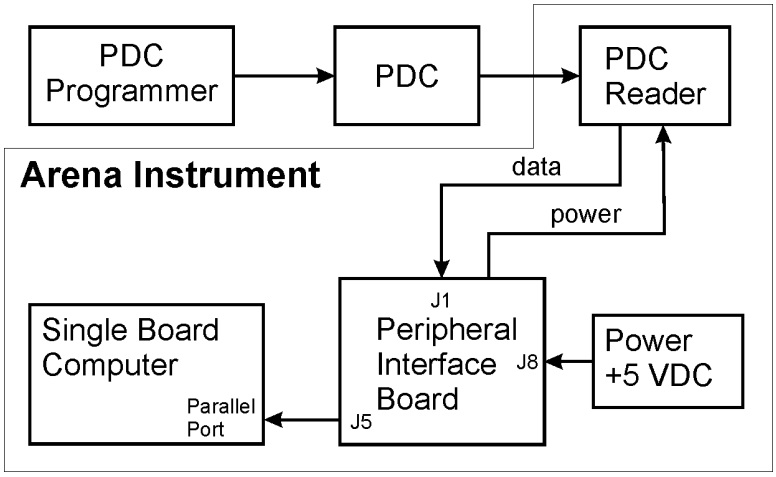

Figure 15-1. PDC System Block Diagram

15.2 PDC PROGRAMMER

This is a separate, independent desktop instrument used to program the PDC. It does not come with the Instrument, so it must be ordered separately.

The PDC Programmer can read and write the card an unlimited number of times. It must be connected to a computer with Renal Soft Software.

15.2.1 Patient Data Card (PDC)

The PDC is the size of a regular credit card, and has an 8192 byte serial memory EEPROM.

The PDC is a protected permanent memory device, which contains patient treatment data. The card may be plugged into the Instrument or removed from it at any time, with power on or off, and with the mode selection in any position. The PDC is programmed using the PDC Programmer. The Arena Instrument can only read the PDC. It does not write to the card.

The PDC can be activated only in Prime Mode. The information on the data card is for input to the Instrument. Once the PDC is confirmed, it may be removed, and the Instrument will continue operating with the information stored from the PDC. If electrical power is lost after the PDC data has been confirmed, regardless of whether the PDC is inserted in the Instrument or not, the Instrument will automatically continue working from the point where it left off for up to 20 minutes with no loss of data.

A PDC can be used in two ways: patient-specific or treatment-typical.

- A patient-specific PDC contains treatment data for one specific patient and is used only for that patient.
- A treatment-typical data card can be set up for any treatment that is commonly used in your clinic and used for any patient whose treatment includes those parameters.

When a patient-specific data card has been used, it is recommended that it be removed from the Instrument at the end of the treatment to prepare the Instrument for the next patient. This will prevent the next patient's being dialyzed on the previous patient's data card information.

Table 15-1 shows the information that must be entered in the PDC, the range and increments allowed, and units used.

Table 15-1. PDC Data Table

	Data Item	Data Range	Increment	Units
1	Prescription Format	1.0	0.1	N/A
2	CSS ID	[0, 9999]	1	N/A
3	Last Name	Unicode Character (must not be blank)	N/A	N/A
4	First Name	Unicode Character (must not be blank)	N/A	N/A
5	Middle Initial	Unicode Character (must not be blank)	N/A	N/A
6	Full Name	Unicode Character (must not be blank)	N/A	N/A
7	Name of Prescriber	Unicode Character (must not be blank)	N/A	N/A
8	Prescription Day	[1, 31]	1	Day
9	Prescription Month	[1, 12]	1	Month
10	Prescription Year	[2001, 2038]	1	Year
11	Prescription Hours	[0, 23]	1	Hour
12	Prescription Minutes	[0, 59]	1	Minute
13	Prescription Seconds	[0, 59]	1	Second
14	Name of Programmer	Unicode Character (must not be blank)	N/A	N/A
15	Date Programmed Day	[1, 31]	1	Day
16	Date Programmed Month	[1, 12]	1	Month
17	Date Programmed Year	[2001, 2038]	1	Year
18	Date Programmed Hours	[0, 23]	1	Hour
19	Date Programmed Minutes	[0, 59]	1	Minute
20	Date Programmed Seconds	[0, 59]	1	Second
21	Blood Pressure Reading Interval	{0, 5, 15, 30, 60}, 0 = Off	N/A	Minute
22	Blood Pressure Max Systolic	[0, 260] (these are alarm limits)	1	mmHg
23	Blood Pressure Min Systolic	[0, 260] (these are alarm limits)	1	mmHg
24	Blood Pressure Max Diastolic	[0, 260] (these are alarm limits)	1	mmHg
25	Blood Pressure Min Diastolic	[0, 260] (these are alarm limits)	1	mmHg
26	Prescribed Blood Flow Rate	If Treatment Mode = DPSND then the range is [50, 330], otherwise the range is [50, 650]	10	mL/ minute

	Data Item	Data Range	Increment	Units
27	Dialysate Flow Rate	[300, 1000] (range can be reduced based on calibration set minimum [300, 500] and set maximum [600, 1000])	100	mL/ minute
28	Standard Sodium	[130, 160] (range can be reduced based on calibration set minimum [130, 138] and set maximum [148, 160])	1	mEq/L
29	Adjusted Sodium	[130, 160] (range can be reduced based on calibration set minimum [130, 138] and set maximum [148, 160])	1	mEq/L
30	Sodium Profile	[130, 160] (range can be reduced based on calibration set minimum [130, 138] and set maximum [148, 160])	1	mEq/L
31	UF Profile	[0.0, 4.0] (range can be reduced based on calibration set minimum [0.0, 0.99] and set maximum [1.0, 4.0])	0.1	L/h
32	UF Only Segments	[0,1]	1	N/A
33	Bicarb Profile	[28, 42] (If Concentrate Type is not Acetate, range can be reduced based on calibration set minimum [28, 38] and set maximum [35, 42])	1	mEq/L
34	Adjusted Bicarb	[28, 42] (If Concentrate Type is not Acetate, range can be reduced based on calibration set minimum [28, 38] and set maximum [35, 42])	1	mEq/L
35	Dialysate Temperature	[35.0, 39.0]	0.1	° C
36	Heparin Bolus Amount	[0.30, 5.00] (range can be reduced based on calibration set maximum [1, 5])	0.01	mL
37	Heparin Pump Rate	[0.0, 5.5]	0.1	mL/hr
38	Heparin Pump Off Time	[0, 120] before end of therapy, 0 = disabled	1	Minute
39	Prescribed Time	[0, 720] (range can be reduced based on calibration set minimum [0, 90] and set maximum [600, 1200])	1	Minute
40	Hemavision Limit	{BV, HCT, None, Machine Setting}, where BV=0, HCT=1, etc., (Instrument setting indicates type of limit currently on machine)	N/A	N/A
41	HCT Limit	[5, 60]	1	HCT
42	Blood Volume Limit	[-80, 0]	1	%

	Data Item	Data Range	Increment	Units
43	Max Na Buttons per Treatment	[0, 7] (range can be reduced based on calibration set maximum [0, 7])	1	N/A
44	DPSND Tidal Volume	[20, 120] (range can be reduced based on calibration set minimum [0, 120] and set maximum [minimum, 120])	1	mL
45	DPSND AV Ratio	[0.5, 2.0] (Represents ratio [1.0:X.X])	0.1	N/A
46	DPSND Needle Volume	[0.0, 10.0]	0.1	mL
47	HDF Target Volume	[0.0, 18.0] (0 indicates option not being used for treatment, and range can be reduced based on a maximum equal to prescribed time maximum HDF rate	0.1	L
48	OLHDF Infusate Volume	[0.0, 60.0], 0 = disabled (range can be reduced based on calibration set minimum [0.1, 3.0] and set maximum [minimum, 60.0]. Range can be further reduced based on a maximum equal to prescribed time maximum OLHDF rate)	0.1	L
49	Treatment Mode	{Standard, Batch HDF, OLHDF, DPSND, SPSND}, where Standard=0, Batch HDF=1, etc. * See Note below this table	N/A	N/A
50	Blood Pressure Monitor Required	{No, Yes}	N/A	N/A
51	UF Profiling Option Required	{No, Yes}	N/A	N/A
52	Sodium/Bicarb Profiling Option Required	{No, Yes}	N/A	N/A
53	Heparin Pump Required	{No, Yes}	N/A	N/A
54	Hemavision Required	{No, Yes}	N/A	N/A
55	Sodium Button Required	{No, Yes}	N/A	N/A
56	DPSND Option Required	{No, Yes}	N/A	N/A
57	HDF Option Required	{No, Yes}	N/A	N/A
58	OLHDF Option Required	{No, Yes}	N/A	N/A
59	SPSND Option Required	{No, Yes}	N/A	N/A

NOTE

In Line 49 of the table above, the Treatment Mode setting must also be compatible with the Option Required settings, as shown in Table 15-2.

Table 15-2. Treatment Mode Setting Compatibility with Option Required Settings

Treatment Mode	HDF Option Required Setting	OLHDF Option Required Setting	DPSND Option Required Setting	SPSND Option Required Setting
Standard	No	No	No	No or Yes
Batch HDF	Yes	No	No	No
OLHDF	No	Yes	No	No
DPSND	No	No	Yes	No
SPSND	No	No	No	Yes

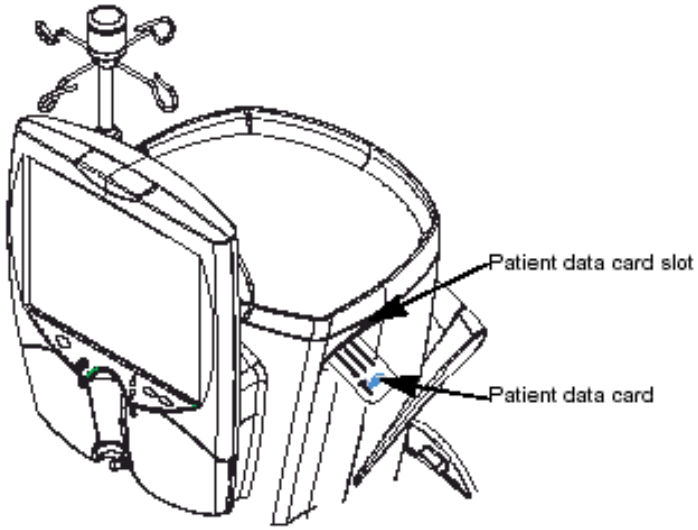

Figure 15-2. PDC Reader Location

15.2.2 PDC Reader

This is the device in the Arena Instrument into which the PDC is inserted and the information is read. The PDC Reader provides a convenient means for initializing the Instrument settings for a particular patient or general therapy. It consists of the actual PDC Reader and the related circuitry on the PIB (Peripheral Interface Board), as shown in the block diagram in Figure 15-1. Their purpose is to automatically read, verify, and load the patient information stored in the PDC (refer to "Load Patient Prescription using the PDC" in the Operator's Manual). The PDC Reader is operational only in the Prime Mode.

The +5 VDC power to the PDC and PDC Reader is provided by the PIB and is protected by Fuse # 2 (see Section 5, Electronic Theory).

An electrical loop is closed when a PDC is inserted into the PDC Reader. The reader is connected to PIB-J1 through a 10-pin connector.

15.2.3 Peripheral Interface Board (PIB)

The PIB consists of Power, Card Inserted Sense, Data and Clock signals for the PDC (refer to Section 5, Electronic Theory). The PIB provides a direct connection between the PDC Reader and the Single Board Computer (SBC). The signals from the PDC Reader enter the PIB through J1 and exit to the SBC through PIB-J5. The PIB also provides +5 VDC and digital ground for the PDC Reader. The +5 VDC is protected by Fuse F2.

There is a red LED (DS1) in the upper left side of the board. This LED should be ON to indicate +5 VDC power to the PIB and PDC.

One additional LED (DS3) is for the Patient Data Card Inserted signal. This is a hardwired signal, regardless of the data on the Patient Data Card.

15.2.4 PDC System Troubleshooting

For any of the PDC error messages, most likely the problem is the PDC itself or the information stored on the card. Follow the operator's manual to troubleshoot it. Use a working card to quickly eliminate the PDC as a potential problem source.

Problem	Probable Cause	Possible Solution
Nothing happens when the PDC is inserted	▪ Not in the right mode of operation ▪ Connector on PIB-J1 is disconnected. ▪ Connectors on PIB-J5 or SBC parallel port may be loose or disconnected. ▪ PDC, PIB or SBC ▪ Fuse 2 is open	▪ Verify the Instrument is in the Prime or Dialysis Mode ▪ Make sure connectors are properly connected. ▪ Check that the +5 VDC indicator DS1 LED on PIB is on ▪ Check Fuse #2 ▪ Check if the "PDC Inserted" LED DS3 on PIB turns on when the PDC is inserted into the PDC Reader ▪ Try a new PDC Reader ▪ Replace the PIB ▪ Replace SBC


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16. PREVENTIVE MAINTENANCE

16.1 OVERVIEW

This section describes routine maintenance required for proper care of the Instrument. Maintenance shall be performed only by Baxter-certified service personnel. As each maintenance procedure is completed, record the date, the serial number, and Instrument hours in a log such as the one found at the end of this section.

Before any adjustments or calibrations are made, the Instrument should be allowed to warm up for at least 10 minutes.

When the annual maintenance is completed, perform a full functional verification (see Section 19) of the system. Ensure that the Instrument has been disinfected (see Section 9) before returning it to clinical use.

WARNING

Before attempting to perform any repair, calibration, or replacement in the hydraulic and pneumatic systems, you must first run a complete disinfection cycle to minimize the risk of contamination. The use of gloves and eye protection is required.

A disinfect cycle must also be run after replacing any parts in the hydraulics circuit.

16.1.1 Supplies Needed

- Clean, dry cloths
- Mild detergent solution (such as mild dishwashing detergent in water)
- Diluted bleach solution (4 parts fresh 5.25% household bleach and 126 parts cold water); for example, 40 mL fresh household bleach and 1260 mL cold water. For use of 6% bleach, see Section 9, Disinfection and Cleaning.
- Cotton swabs
- Silicone base O-ring lubricant
- Gloves resistant to the disinfectant
- Face shield or safety glasses
- Gloves

16.1.2 General Preconditions

- Fluid path and external surfaces disinfected
- Power cord is plugged into the wall socket
- Mains power switch is off
- Water supply off
- Hydraulics module is open

  To ensure that the hydraulics module stays open, wrap one of the concentrate lines around the hose cleat as shown in Figure 16-1, then reconnect it to the rinse block. It may be necessary to push the hose back into the side panel to shorten it until there is enough tension to hold the door open.

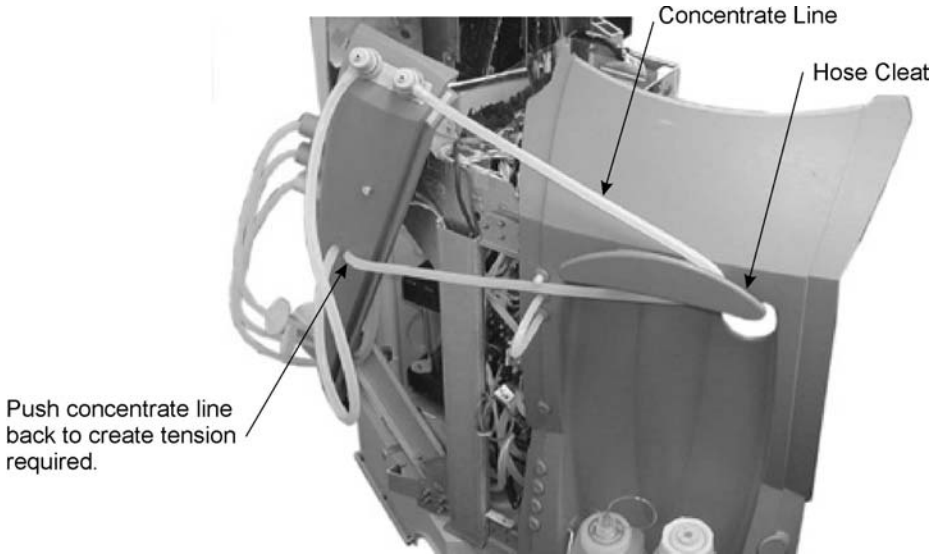

Figure 16-1. Securing the Back Door

16.2 RECOMMENDED MAINTENANCE

16.2.1 Routine

Any time other work is being done on the Instrument, the following should also be done.

- Check and repair, replace, adjust or tighten as required:
  - Hydraulic leaks
  - Worn parts
  - Loose parts and connections
  - Discolored wires, terminals, relay contacts, and tubing
- Inspect valves, switches, motors, relays, circuit breakers, etc., for signs of water leaking onto the component. Replace wetted components.
- Clean or replace concentrate line filters
- Inspect concentrate fitting O-rings and replace as needed
- Inspect dialyzer connector O-rings and replace as needed
- Check fan filter and clean or replace as needed

16.2.2 Annual

- Replace internal arterial and venous level adjust/pressure monitoring system transducer protectors.
- Replace UF flow meter diaphragm (J040700).
- Clean Instrument interior (including dust removal and fan filter).
- Clean blood leak detector lenses.
- (**Every two years**) Replace flow equalizer diaphragms (J0171700).
- Perform all functional verifications (see Section 19), and calibrate as necessary.

16.2.3 As Required by Local Code

Check:

- Line cord ground continuity
- Leakage current

16.2.4 Before Prolonged Storage

- Disinfect and drain the fluid path.

Refer to Section 9, Disinfection, for fluid path disinfections, and Section 28, Installation, for instructions on long-term storage.

16.3 CLEANING PROCEDURES

16.3.1 Clean Blood Leak Detector

Procedure

1. Put a container under the Blood Leak Detector Drain Line and turn the blood leak detector plug counterclockwise a quarter turn, wait for the detector to drain, then remove the plug.
2. Clean the inside of the detector housing and the inner side of the detector plug.
3. Apply a thin film of silicone base O-ring lubricant on the plug O-ring.
4. Reinsert the plug by aligning the pins with the grooves and turning the plug clockwise a quarter turn.
5. Recalibrate as described in Section 18, Calibration Procedures.

16.3.2 Clean Hydraulics Module Overflow Drain and Drain Line

Make sure that the drain/drain line is not plugged or otherwise obstructed.

16.3.3 Clean Fan Filter

WARNING

To prevent possible injury, the Instrument must be hard powered off (mains power switch off) before working with the fan(s). The fan(s) may start without warning if the instrument is soft powered off.

1. Remove the fan filter by pulling out the retainer from underneath the Instrument. (See Figure 16-2.) No tools are required for filter removal.
2. Wash and rinse filter under running water.
3. Dry filter.
4. Reinstall filter.

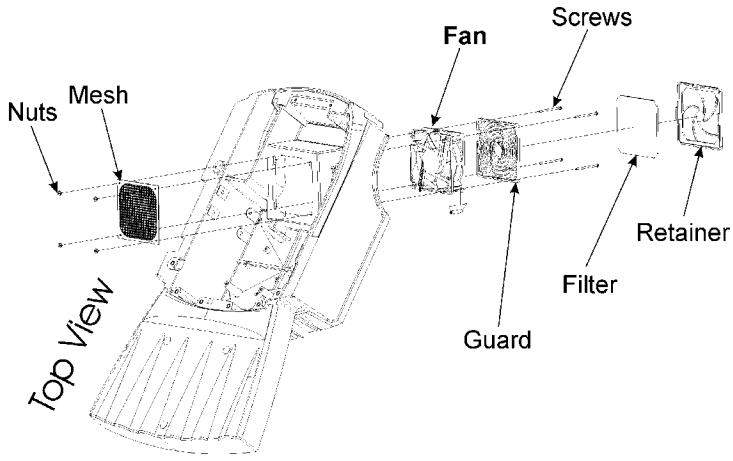

Figure 16-2. Fan Filter Location

16.3.4 As Required

Clean:

- External surfaces
- Concentrate and disinfect line rinse ports and rinse block
- Fan filter
- Hydraulics Module Overflow Drain/Drain Line

Lubricate (with silicone base O-ring lubricant)**:**

- O-rings, such as concentrate and dialyzer connectors

Replace:

- Particle filters

16.4 O-RING REPLACEMENT

16.4.1 Overview

The service life of the O-rings in both the dialyzer connectors and the concentrate connectors depends on several factors, such as type and strength of disinfectant used and the frequency of usage.

16.4.2 Dialyzer Connectors

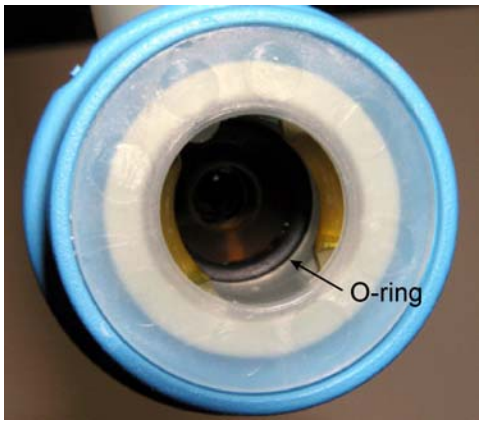

Figure 16-3. Dialyzer Connector O-ring

16.4.3 Concentrate Connectors

Figure 16-4. Concentrate O-ring Location

16.5 PARTICLE FILTER REPLACEMENT

16.5.1 Overview

The service life of the particle filters depends on the rate at which material collects on the filter screens, increasing the filter pressure drop. Ultimately the performance of the Instrument may be affected.

If filter clogging is due to precipitation of dialysate in the fluid path, the filters must be replaced as part of the fluid path cleaning process.

Signs and symptoms of clogged filters:

If the clogging is caused by gradual buildup of particles on the filter screens, the first symptoms will be increasing occurrence of FLOW RESTRICTED alarm messages. Initially these will only be seen at maximum dialysate flow rates, and as the clogging progresses, will be observed at progressively lower flows. Clogging is not likely to be detected by self-test unless the test is performed at high flow rates.

CAUTION

If clogging is the result of massive precipitate formation in the fluid path (such as might be caused by improper concentrate selection or preparation errors), particle filter backpressure will increase as well. In these cases, acid rinses or heat clean cycles will not entirely remove the precipitates in the filters. The filters must be replaced.

WARNING

Cleaning and reuse of the particle filter is not recommended.

16.5.2 Particle Filters

Supplies needed

- Particle filter, J400100, 2 each

CAUTION

To prevent possible hydraulic line blow off, use a hose clamp to secure the hydraulic lines to each side of the particle filters.

Postdialyzer filter:

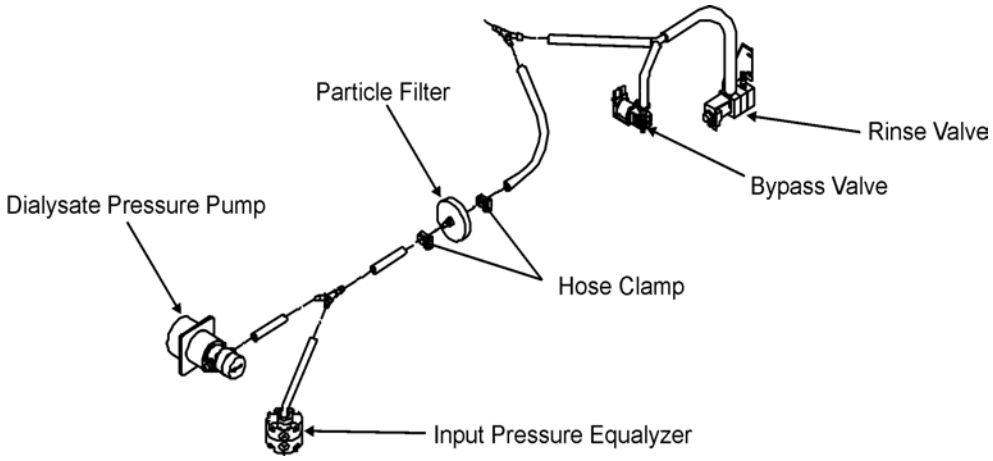

Figure 16-5. Postdialyzer Particle Filter

Predialyzer filter:

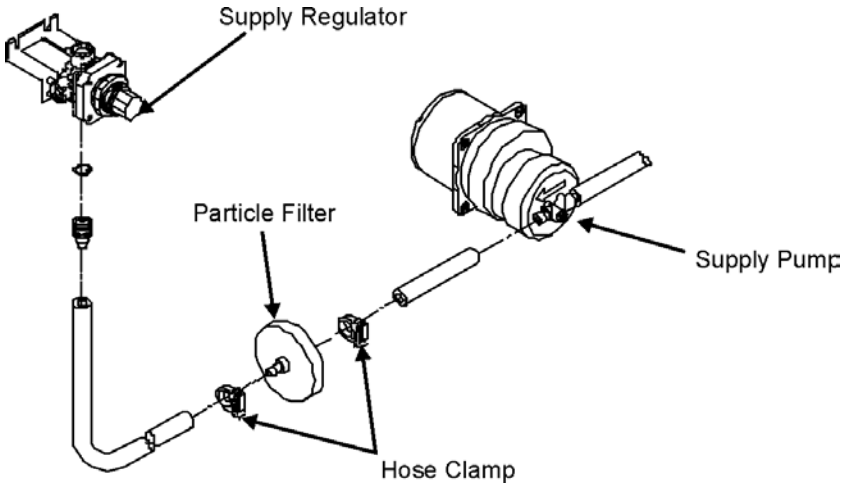

Figure 16-6. Predialyzer Particle Filter

16.6 FLOW EQUALIZER DIAPHRAGM REPLACEMENT

These diaphragms should be replaced every **two** years during the annual maintenance. Establish the General Preconditions (Section 16.1.2). Both diaphragms must be replaced at the same time.

Whenever the valves are removed, they must be reinstalled in the same orientation as shown in Figure 16-7.

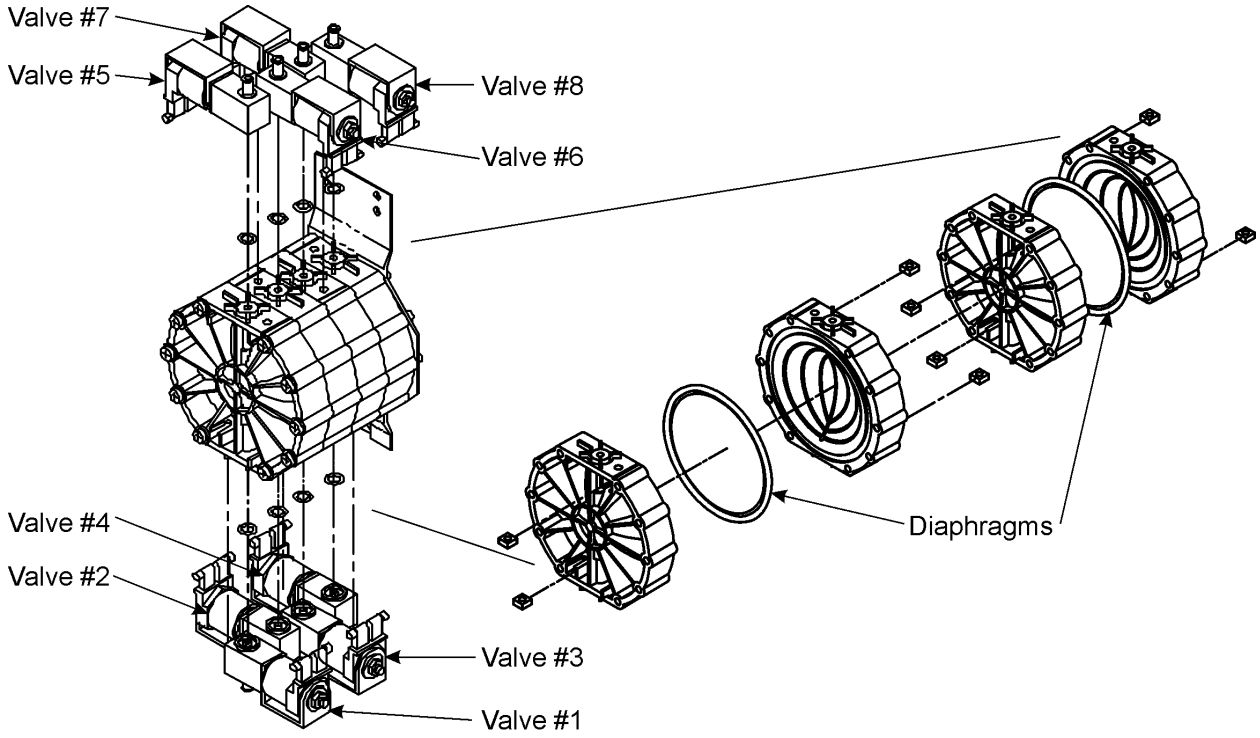

Figure 16-7. Flow Equalizer and Valves

16.7 UF FLOW METER DIAPHRAGM REPLACEMENT

This diaphragm must be replaced during the annual preventive maintenance. Refer to Figure 16-8.

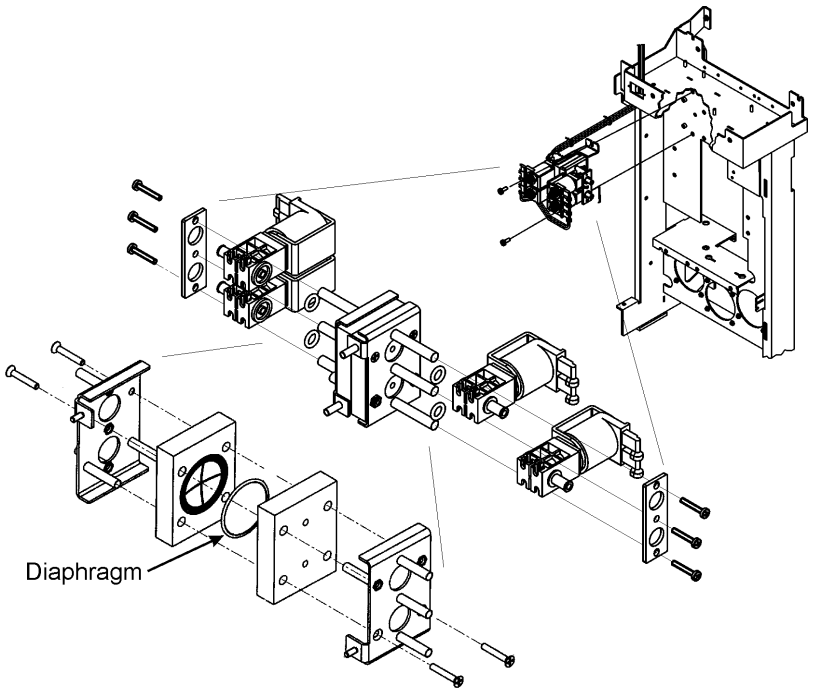

Figure 16-8. UF Flow Meter Diaphragm Location

16.8 A/V PRESSURE TRANSDUCER ASSESSMENT AND DISINFECTION PROCEDURE

Whenever blood contamination occurs, it will be necessary to replace affected level adjust and pressure monitoring components.

Read these instructions in their entirety before beginning component replacement.

Note

Observe Universal precautions.

16.8.1 Additional Supplies Needed

In addition to the supplies listed in Section 16.1.1, the following will be needed for transducer replacement (16.8.3). See Figure 16-9.

- Observe Universal Precautions.
- Handle biohazard waste per clinic procedures.

1. Fitting, tee, 116122
2. Fitting 1/8”, Luer, male, P0261000
3. Filter, A02830000, also called a transducer protector
4. Fitting 1/8”, luer female, P01670000
5. Tubing, PVC, 1/8” ID, T00050000 (sold by the foot)
6. Fitting, luer connector with nut, P038200

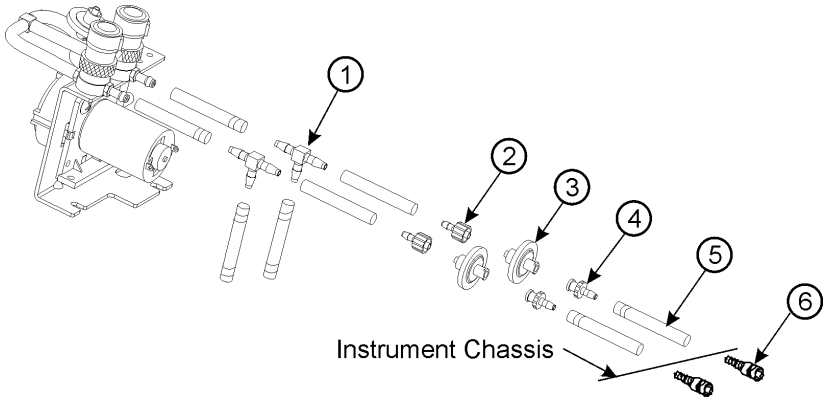

Figure 16-9. Arterial/Venous Pressure Monitoring System

WARNINGS

Care should be taken when handling blood contaminated components to prevent contamination of personnel or other devices.

Handle used blood lines, dialyzers, transducer protectors, and blood contaminated components as potentially biohazardous waste. Refer to the clinic's procedures for the disposition of these items.

Make sure that the replacement of blood-contaminated components is performed in an isolated area to help prevent contamination of personnel and other devices.

Make sure that all tools used to handle, access, remove and/or replace blood contaminated components are disinfected when the job is done to prevent contamination of personnel and/or other devices.

CAUTIONS

Static discharge may damage electronic components.

Both MOS and Bipolar integrated circuits may be damaged by discharge of static electricity.

Both digital and linear integrated circuits may also be damaged.

Static damage may occur not only to integrated circuits mounted on the circuit board, but also to detached integrated circuits.

Static damage may not be immediately evident.

Static damage is cumulative.

Do not remove or plug in any electronic component or assembly while power is applied to the Instrument.

It is necessary to perform some of the adjustments with the covers removed. Use extra care to prevent fluids from entering or contacting the electronics of the Instrument.

Use proper ESD protection when handling or contacting any ESD sensitive components.

Always repackage the removed ROMs or boards in the original ESD packaging.

Perform work using standard ESD precautions including personal grounding strap.

16.8.2 Contamination Assessment Procedure

If during the dialysis treatment the external transducer protector is wetted, and blood is visible on the Instrument side of the transducer protector, then the Instrument must be removed from service at the end of treatment, and a qualified technician must assess the Instrument for contamination using the following

procedure. Reference numbers in the following steps refer to Figure 16-9.

Note

If there is contamination detected anywhere during the following assessment procedure, then perform the disinfection procedure described in Section 16.8.3.

1. Wipe the exterior of the metal luer connector (6) that was connected to the wetted external transducer protector, and inspect for evidence of blood.
2. Establish the General Preconditions (Section 16.1.1).
3. Assess the affected arterial and venous pressure system.
    a. Place a white card behind the tubing (5) connecting the metal luer connector (6) and the internal transducer protector (3 & 4) for contrast purposes, and inspect for evidence of blood in either the tubing (5) or the internal transducer protector (3 & 4).

Note

In order to gain access to the internal transducer protector, you may have to remove the card cage. See Section 16.8.3, Step 3, for instructions.

    b. Remove the internal tubing from the metal luer connector.
    c. Insert a white pipe cleaner dampened with alcohol into the metal luer connector and pull completely through and inspect for evidence of blood.

16.8.3 Transducer Protector Replacement and Disinfection Procedure

1. Carefully inspect the entire level adjust and pressure monitoring tubing set for blood. Replace all contaminated components.
2. Disconnect contaminated tubing from the pressure (luer) fitting(s) on the inside of the Instrument.
3. Remove and replace the fitting(s).

    In order to gain access to the luer fittings, it may be necessary to adjust or remove the card cage.

    - To move the card cage, loosen the four corner screws then slide the cage on the screws in the key-hole shaped mounting holes.

- Perform work using standard ESD precautions including personal grounding strap.
- Before disconnecting any cables, note their position. Mark as needed.

4. Disconnect the other end of the contaminated tubing from the filter(s).
5. If the filter is contaminated, replace it.

   Carefully inspect the entire tubing set for blood. Replace all contaminated components. Since you can not inspect the interior of the transducer manifold, solenoid valve and valve manifold (as applicable), these components may need to be replaced if the filter is contaminated.
6. Connect new tubing between the filter(s) and the pressure fitting(s).

Arena Hemodialysis System

MAINTENANCE LOG

Clinic: _____ Completed by: _____

S/N_____ Date _____ Instrument Hours_____ Next PM _____

Maintenance

Parts Serviced:	Replaced	Cleaned
Blood leak detector		
Overflow Drain & Drain Line		
Fan Filter		
Dialyzer connector O-rings		
Concentrate fitting O-rings		
Postdialyzer Filter		
Predialyzer Filter		
Concentrate line filters		
Flow equalizer diaphragms		
UF flow meter diaphragm		
Internal A/V transducer protectors		

Other parts used:

Calibration

Use Calibration Worksheet at the end of Section 18.

Functional Verification

Use Functional Verification Data Sheet at the end of Section 19.


Arena